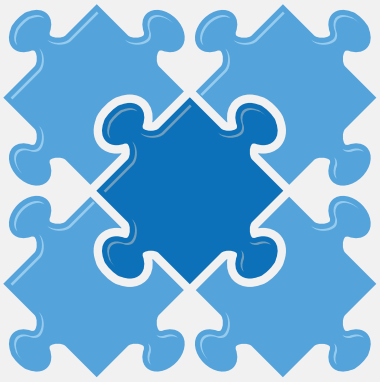
1st Annual Presidency Congress
Waterfront Belfast
27-30 November 2017



European Alliance for Personalised Medicine

'Personalising Your Health: A Global Imperative'

Congress report

European Alliance for Personalised Medicine

EAPM

2nd Annual Congress, MILAN

The European Alliance for Personalised Medicine (EAPM) is already planning a second major, personalised medicine Congress in Milan on November 26–28, 2018.

Similarly to the inaugural 2017 Congress in Belfast, this will be a pan-European, multi-disciplinary event specific to the fast-moving field of personalised medicine and will take place from 26–28 November 2018

EAPM and its stakeholders believe that Europe needs to build better healthcare systems for its current 500 million citizens, and the generations to come.

A key aim of the Congress is to allow cross-fertilisation between the different disease and policy areas, allowing delegates to gain a greater depth of knowledge into barriers in the field of personalised medicine.

It is also geared towards offering up valuable evidence and stakeholder opinion on which policy makers can base their decision making on how better to integrate personalised medicine into the EU's healthcare services.

The event will provide the biggest 'space' to date to allow for such a meeting of minds and expertise, and EAPM is building a one-stop-shop for top-level discussion and the formulation of real action plans. So be sure to come.

Once again, the Congress will bring together the different streams (including scientists, industry, regulators, patients and more) in order to allow decision makers to understand changes that are required, now and down the line.

The Congress will pull together leading experts in the arena of personalised medicine drawn from patient groups, payers, healthcare professionals plus industry, science, academic and research representatives.

For more information, please contact the EAPM Office:
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Executive summary

Late November saw the opening of the first annual Congress held by the European Alliance for Personalised Medicine (EAPM).

The four-day event, entitled '*Personalising Your Health: A Global Imperative*' was held in the capital of Northern Ireland under the auspices of the Estonian Presidency of the EU and in association with Queen's University Belfast and Visit Belfast.

It was the first ever pan-European, multidisciplinary Congress specific to the fast-moving field of personalised medicine and a resounding success. It provided the biggest 'space' to date to allow for such a meeting of minds and expertise.

We are delighted to say that the event had ***650 registered attendees, 250 speakers and displayed around 200 abstracts across the week. We also sent out around 1,000 tweets.***

Congresses represented a one-stop-shop for top-level discussion and the formulation of real action plans. It dove-tailed with the ongoing, multi-layered policy goals of the Alliance, given that a founding principle of EAPM was, and is, to bring together all stakeholders allowing us to find consensus where possible and also allowing us to speak in a constructive language that regulators and institutions understand.

EAPM will continue to do this and, over five years, has achieved many successes through such methodologies, not least through our five annual conferences.

The future of healthcare is arguably already right here, right now - due to great leaps in gene and other technologies, Big Data and personalised, targeted medicine - yet the environment is still shifting rapidly.

There remain opportunities alongside difficult challenges when it comes to embedding personalised medicine into Europe's healthcare systems down the line.

Realistically, we are still a fair way off achieving that. But with European Parliament elections no longer too far away and at a time when Europe is trying to consolidate during changing times (Brexit, for example), there is no reason why up-to-the-minute healthcare should not be in the minds of many as the EU attempts to redefine itself.

It is clear that in the case of medicines and treatments, one size definitely does not fit all. We know that certain treatments or combinations may produce excellent results for some patients, yet fail miserably for others. Side-effects can also vary. This can lead to unnecessary suffering and has a huge impact on costs.

For example, many cancer patients do not react positively to chemotherapy, and genetic testing can highlight this issue, as well as leading to preventative measures.

In the latter case, the same can said for screening programmes.

Why personalised medicine?

Personalised medicine offers the promise of seeing healthcare move away from 'trial-and-error' therapies to evidence-based individual ones. Down the line, healthcare services will increasingly deliver the right intervention when appropriate, improving the outcomes for patients and cutting down on unnecessary treatments.

Personalised medicine can also reduce trial-and-error prescribing, minimise adverse reactions to drugs and cut down on invasive testing methods.

It is important to note that personalised medicine is not just another addition to the understanding and practice of medicine - the art that concerns itself with the prevention, diagnosis and treatment of disease. It has the potential to significantly alter medicine itself.

EAPM has pulled together key policy assks that emerged, through consensus, during Congress. The Alliance intends to, as ever, pass these on to the European Commission, Parliament and Member State healthcare officials.

It is clear that we need to engage at all political levels and, as ever, the Alliance will do this in its role as a platform for all stakeholders in the arena of personalised medicine.

The European elections and a new Commission are not so far away now, and that it is more important than ever that messages get across to those who will have influence down the line.

As was pointed out many times in Belfast, we need action at EU level. But the EU can do little if it doesn't listen to stakeholders, and neither can it do much if stakeholders cannot speak as one.

We need, as a unit, to get our ideas across to policymakers and legislators. We must tell them what we need to succeed going forward, and explain what is necessary to turn the dream of personalised medicine into a solid, practical and sustainable reality.

David Byrne - EAPM Co-chair
Gordon McVie - EAPM Co-chair
Denis Horgan - EAPM Executive Director

Overview

The Belfast Congress had many highlights, not least the fact that EAPM has now been involved in two sets of Council Conclusions that will have an impact on the future of health in general and targeted treatments and diagnoses in particular.

The first of these was, of course, the landmark Luxembourg conclusions on access to personalised medicine two years ago.

These came about in no small part due to EAPM's influence and involvement, not least at a major conference on the topic at the start of the Luxembourg presidency, organised by the Duchy's health minister Lydia Mutsch and her team.

Now we have the 'Draft Council conclusions on Health in the Digital Society - making progress in data-driven innovation in the field of health', under the auspices of the Estonian presidency which runs until the end of 2017.

Many of these conclusions echo those reached at EAPM's several conferences and particularly those reached at our first Congress in November with which this booklet is primarily concerned.

The potential for personalised medicine to significantly alter the healthcare landscape cannot be understated.

Science is moving very quickly in this field and the EU is currently playing catch-up. This has to change, and soon.

We all have a part to play, and that includes the European Commission, Parliament and Member State health ministers.

While we see many exciting opportunities in this dynamic field, the fact remains that there are still many barriers to overcome on the road to full integration of personalised medicine. Cooperation and collaboration between all stakeholders - including politicians and policymakers - is vital moving forward.

We live in a Europe facing real health issues. Ageing populations and, thus, patients suffering from one or more chronic diseases, are putting unsustainable pressure on healthcare systems across the EU.

Meanwhile, new processes for clinical trials need to be put in place (especially in the sphere of rare diseases), cross-border healthcare needs more and better take up, eHealth records need to overcome interoperability issues and synergise, general access for patients to the best treatments available needs to be drastically increased, and ongoing education for healthcare professionals must be boosted.

Also, regulations must be updated in order to be fit-for-purpose at a time when Big Data could greatly improve healthcare, if used efficiently and ethically, and huge leaps in medical science are continually occurring.

Reimbursement and incentives need to be seriously looked at to encourage innovative new treatments, the definition of 'value' needs to be agreed, and bench-to-beside timeframes for new products need to speed up dramatically.

As explained earlier, central to personalised medicine is the fact that Europe's patients need to be empowered and put at the centre of their own treatment decisions, working with their healthcare professionals in a valuable dialogue.

EAPM's goals include the following:

- Ensuring a regulatory environment that allows early patient access to novel and efficacious personalised medicine
- Increasing R&D for personalised medicine, while also recognising its value
- Improving the education and training of healthcare professionals, while increasing awareness and understanding of personalised medicine
- Supporting new approaches to reimbursement and HTA, required for better patient access

All of the above issues and more were discussed at Congress, as you will see on the following pages.

Simon Harris, Minister of Health, Republic of Ireland, speaking at the opening of Congress

Some Key Policy Asks and Needs

Concerning Big Data

There is a need to:

- Break silos of single-use data and remove country-specific gridlocks
- Use technology to strengthen data security but also to ease access and consent - such as through electronic medical records and e-consent
- Build initiatives that improve trust, and educate and empower participants to influence research
- Establish clear lines of accountability, with strong baseline protection that also provides opportunities for data access
- Allow re-use and secondary use of data for scientific and regulatory purposes
- Devise a regulatory environment that resolves complex data protection rules currently impeding biomedical progress
- Build acceptance of certified Cloud environments

Innovation and Research

There is a need for:

- New business models geared toward benefiting patients, society, industry and healthcare budgets
- Support for PPs that work to promote multi-stakeholder collaboration
- Regulatory and legislative change that reflects the realities of innovative science and the needs of citizens
- More and better incentives for business models that ensure early patient access to health innovations
- More systematic engagement of patients
- Translation from basic research to clinical research: This requires open research collaboration mechanisms. It also requires a supportive European legal framework on research enablers
- Translation from research to development of innovative healthcare products: to incorporate the patient perspective and new sciences/genome-based knowledge and technologies into a more flexible adaptive development model
- Translation from development to healthcare delivery and access: new understanding of disease biology and earlier patient access would also require changes to the way healthcare delivery and reimbursement of health services are organised
- Incentivisation of research investments

And Europe must:

- Update the basic processes of R&D and regulation to allow evaluation of clinical effectiveness and analyses of long-term treatment outcomes using real-world data
- Integrate new knowledge into regulatory pathways
- Simplify and speed up regulatory procedures, while taking account of diagnostics
- Review systems to incentivise innovation through novel methodologies for benefit-risk evaluation and reimbursement

Meanwhile, we need:

- Mush more predictable systems to cut costs and speed up patient access
- To allow the collection, pooling and mining of relevant information on benefit and risk
- More pro-active use of conditional authorisation and reduction of uncertainty in adaptive authorisation models
- Recognition by payers of the need to reward innovation
- Faster reimbursement decisions
- To ensure that marketing authorisation findings are used as the basis of HTA, and that the findings are translated
- Align post-approval requirements across decision-makers
- Coordinate assessment and reimbursement mechanisms for drugs and diagnostics

Marian Harkin, MEP

- Identify, by means of research and testing, new pricing and reimbursement models which include patient relevant outcomes and reflect the value of new medicines to society

- Open collaboration in multidisciplinary research partnerships that cross sectors and borders and stakeholder groups

- Provide support for neutral brokers to ensure equity and quality in partnerships

- Seek out adventurous approaches to the development of new medicines that partnerships are best placed to adopt.

Regulation

- The legal framework in Europe is complex and heterogeneous, and is hampering international clinical research

- Divergent legislative requirements should be harmonized, and the related costs and administrative burden should be reduced

- Complex and inflexible procedures need to be simplified and made more predictable

- Legislators need to ensure the consistency of distinct sets of legislation addressing the obligations of sponsors and researchers, relating to authorisations, data protection, the use of tissue, medical devices, in-vitro diagnostics and more

- Patients should be allowed earlier access to innovative medicines

- Adaptive clinical trial methodologies must be adopted

- Smart but robust clinical research methodologies need to be developed and endorsed by regulators and payers

There is a need for:

- Greater coherence between the different regulatory and reimbursement pathways for diagnostics and medicines

- Change is needed to ensure that a companion diagnostic and its corresponding medicine are assessed in a coordinated way

- Formal regulatory acknowledgement of the significance of companion diagnostics, and rigorous but proportionate review, duly coordinated with review of corresponding medicines

- More incentives and greater allocation of time and resources to developing companion diagnostics

- A harmonised EU regulatory framework balancing patient safety with access to innovation

- A more effective clinical trials regime

- Coordination of reimbursement for medicines and companion diagnostics

Screening and Guidelines (lung cancer)

Findings in both Europe and the US strongly suggest that lung cancer screening works. Ideally, guidelines could help to tether costs, by bringing in improvements to the efficiency of screening methodologies and, thus, programmes themselves.

We need to:

- Make the best use of efficient risk-assessment methods

- This includes top-of-the-range imaging technology utilising volumetric protocols, and clinical work-up guidelines that encourage the minimisation of invasive procedures and risk to the patient

- Put in place that will allow Member States to set-up quality assured early detection programmes for lung cancer

- Raise awareness of the need for agreed recommendations over lung-cancer screening at the highest political levels

- Improve the knowledge of policymakers and world health agencies so that effective lung-cancer screening guidelines and policies can be formulated on the international stage

- Work across national borders to ensure cooperation and collaboration in respect of much-needed guidelines, especially in the fast-developing field of personalised medicine

- Advance parallel work done by professional groups, patient groups, healthcare funders, pharmaceutical companies and academic institutions to a new level

Denis Horgan, EAPM Executive Director, who opened the Congress

- Use data emerging from screening programmes to advance early lung-cancer care and research on a worldwide level

- Engage with industry, academia, patient groups and other stakeholders regarding research and other key areas

Screening for blindness

There are some 39 million blind people in the world, but 80 per cent of blindness can be cured or prevented.

There is a need for:

- A more preventative approach to blindness across the EU's Member States

- Recognition that the battle against eye disease in Europe to be fought at EU level

- Acceptance of the fact that studies suggest that eye disease costs society in Europe some €20 billion, causing a significant economic burde

- Understand that many of these costs are due to day-to-day care for the blind by relatives and friends. This, therefore, has an impact on society as a whole, not just on the sufferer

Education of HCPs

Personalised medicine starts with the patient. It holds huge potential for improving the health of many patients and ensuring better outcomes of health systems' efficiency and transparency.

Part of what is required is a long-term approach to education to ensure the translation of new therapies from laboratories to patients.

Therefore, we need to:

- Ensure that all HCPs in close contact with patients or their patients' families are up-to-date with the current aspects of personalised medicine and its latest breakthroughs in order to better understand their patients' concerns

- Recognise that an improvement in such skills among HCPs is vital to giving the right treatment to the right patient at the right time

It is clear that:

- None of the advances in personalised medicine will benefit patients if they are not applied or not applied correctly.

- HCPs must be aware of these fundamental and rapid changes in medicine

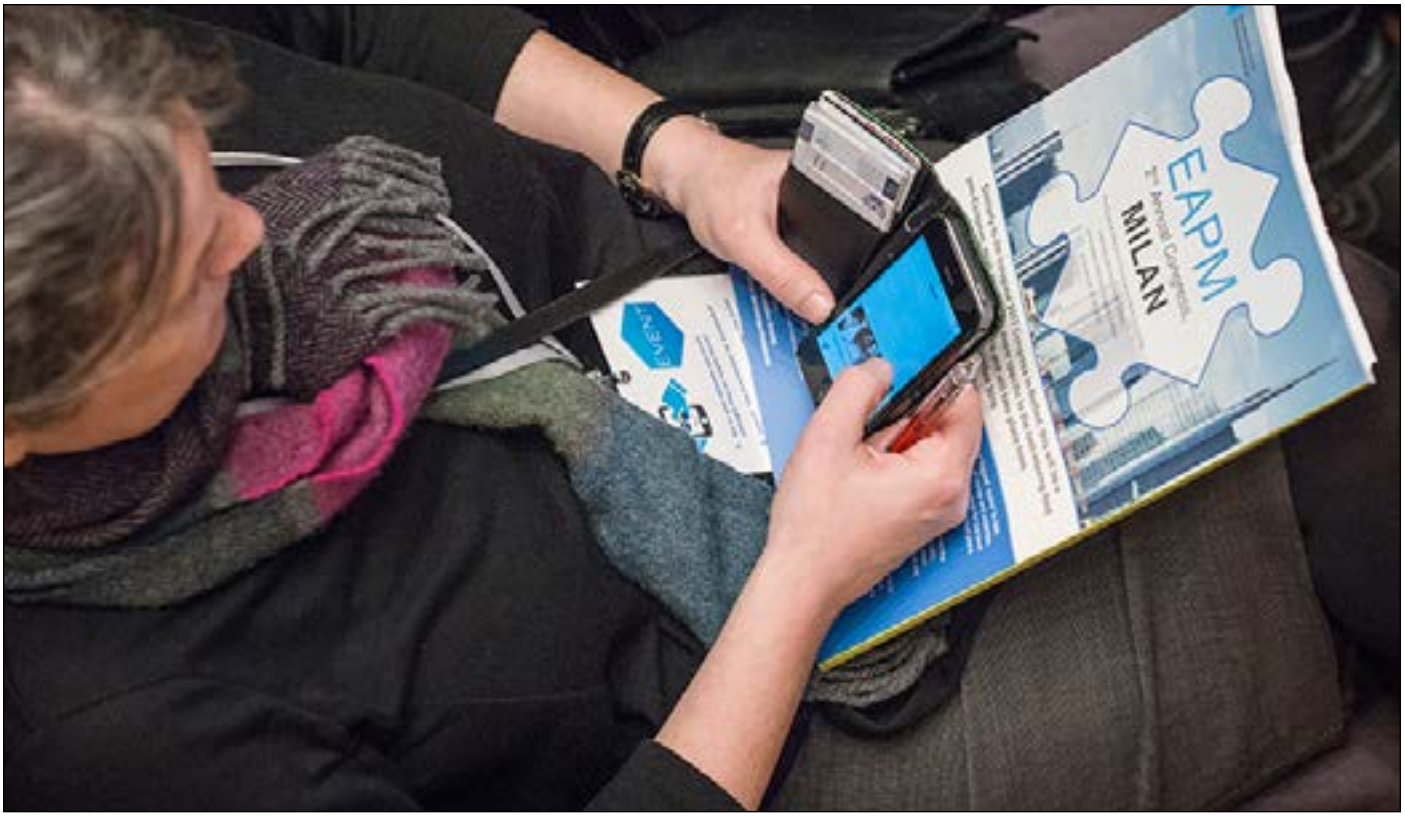
- Some HCPs, lab technicians for example, will need a thorough training in novel diagnostic approaches

- Meanwhile, other HCPs, certain medical specialists for instance, must know what tests are available, understand when a patient is eligible for such a test, and be able to interpret the data

- At the same time, HCPs must be capable of navigating the ethical, legal and social issues that, for instance, surround the use of genetic testing

- HCPs must be able to adapt the way in which they attain knowledge and skills to accommodate the rapid advancement in science, which, in turn, impacts exponentially on the availability of diagnostic tools and tests and treatment option

- Patients will miss out on the benefit of this valuable knowledge if HCPs do not have the skills to identify, translate and utilise this knowledge to diagnose and treat their patients



Keeping the Person in Personalised Health

2016 was certainly an interesting year with at least two major political upsets, namely Brexit and the US presidential election result. Uncertainty has followed us throughout 2017.

Civic unrest, hate crimes, denial, the blame game and more ensued. For many people, these testing times are offering up more fear than they are hope, despite great leaps in technology as well as more involved, knowledgable and, thus, empowered patients.

Congress heard that there is still much discrimination in healthcare (on both sides of the Atlantic) and there is a real need to ensure inclusivity and make certain that technology is integrated to allow for the right treatment for the right patient at the right time.

We must look at how to realise the promise of the patient-centred approach. Better methods of treatment and treatment education need to help the person at the level of the person.

Modern technology and the information highway have created new ways to put the patient at the centre of medicine.

Giant leaps in genetics have advanced certain key areas in healthcare, and have also led, at least in theory, to more patient empowerment. If people with serious diseases are to make informed decisions about their health, it is vital for them to have the necessary knowledge and support.

DNA tests, for example, can throw up in advance the various likelihoods of major illnesses happening in an individual, although of course not everybody wants to know that they may have more chance of getting breast or colon cancer than their neighbour.

Genetics has, as mentioned, opened new doors for patients in the form of personalised medicine. It has often changed the 'patient journey', with new treatments available and better communication between doctors and patients.

As we know, personalised medicine aims to offer the right treatment to the right patient at the right time. Diagnosis of the disease based on its molecular image will allow clinicians to select the most effective pharmaceutical, for example, while pharmacogenetic assays will make predicting the patient's response to treatment much easier.

The beginnings of implementing any new idea are difficult, but proponents of personalised medicine, in all fields, are aware of the duty to talk about better medicine, giving not only hope but leading to longer survival rates of more patients with better quality of life.

These days, there is more co-decision as lifestyle, work and personal preferences come into play, or should do, especially with front-line healthcare professionals who are up-to-speed with the latest developments, or know where suitable clinical trials are taking place and actually pass this on to their patients.

Patients are pushing to play a bigger role. And despite some who don't believe that they should be doing so, it is a fact. Stakeholders in personalised medicine are carrying the message "Involve me!", and it is never the best policy to 'shoot the messenger'

Congress heard from key speakers aiming to get to grips with precision medicine.

Attendees were told that we have more than enough data in the medical world, but we don't share enough of this data. We must align stakeholders' interests with our common goal, namely the very best health care that can be provided.

Although the patient experience is extremely important, they should not be the sole focus. We need to look at the broader needs of society. A more sustainable approach is to look at

A warm welcome to all at Belfast City Hall

Speakers and delegates gathered last night for a reception at Belfast City Hall, featuring an award ceremony and an address by Parliamentary Under Secretary of State for Northern Ireland, Chloe Smith MP (top right).

Chloe is pictured again bottom-left with David Boyd of AstraZeneca and Malta's deputy prime minister Chris Fearne. The EAPM SMART Award (Smaller Member states And Regions Together) went to Malta, while the Patient-centric Innovator Award went to AstraZeneca. *Pictures by Simon Pugh Photography*

prevention. We need to start concentrating seriously on prevention, where pharmaceutical companies have a huge role to play and have had great success with vaccination programmes.

Precision medicine allows doctors and researchers to predict more accurately which treatment and prevention strategies for a particular disease will work in which groups of people.

It is in contrast to a one-size-fits-all approach, in which disease treatment and prevention strategies are developed for the average person, with less consideration for the differences between individuals.

Although the term 'precision medicine' is relatively new, the concept has been a part of healthcare for many years.

For example, a person who needs a blood transfusion is not given blood from a randomly selected donor; instead, the donor's blood type is matched to the recipient to reduce the risk of complications. Although examples can be found in several areas of medicine, the role of precision medicine in day-to-day healthcare is relatively limited. Researchers hope that this approach will expand to many areas of health and healthcare in coming years.

Points to consider:

- Personalised medicine offers the promise of healthcare moving away from 'trial-and-error' therapies to evidence-based individual ones, removing the outdated 'one-size-fits-all' philosophy

- Down the line, healthcare services will increasingly deliver the right intervention when appropriate, improving the outcomes for patients and cutting down on unnecessary treatments.

- Personalised medicine starts with the patients, and holds huge potential for improving the health of many of them

Personalised medicine and cancer

The phrase 'prevention is better than cure' is well known. Although often used as a metaphor, its literal meaning has some substance.

If every disease could be prevented before it began, then the improvements in the long-term health of citizens would be assured and the savings for healthcare services would be enormous.

Personalised medicine can go some way to achieving this, with genome sequencing having the ability to spot a tendency to develop a certain disease down the line. Vaccinations and screening for breast, prostate and - in this case - lung cancer, for example, can also bring this about.

Resources are of course limited - every healthcare system across the world is struggling to keep pace with the new demographics - and there needs to be a substantial, 'smart' shift in the way these services spend what money they have.

Putting more emphasis on preventative measures is one way to do this.

Currently, certainly in Europe, not only are patients failing to receive the best care, there is potential to cause them preventable harm.

It is clear that investment is required in diagnostic approaches, such as the use of IVDs and more screening, certainly in lung cancer (of which more later).

Also, up-to-the minute education is desperately needed for healthcare professionals who are facing a brave new world in which personalised medicine is a game changer. They need to understand what is now available (including next-generation sequencing, or NGS), as do their patients.

Fortunately, treatment and medicine is moving from health professional-led decision making to evidence-based shared decision making. A number of European guidelines have been developed in specific disease areas, such as in urology,

Chris Round, Merck

respiratory medicine, gastroenterology and cardiology. But it is still important to address the major gap in engagement between the scientific community and key stakeholders as users/beneficiaries of guidelines.

Well-informed healthcare professionals and unified guidelines will play a key role in harmonising care but this requires awareness building and training.

Work needs to continue in all areas to agree and publicise guidelines in the complex and developing world of personalised medicine and to identify illnesses early on.

Treating patients is often not an easy task - difficult decisions need to be made, often in the face of uncertainty.

But clinical guidelines exist to help, including recommendations aimed at optimising patient care. They are based on evidence, systematically reviewed, but it can even then be difficult to assess which are the best.

Doctors need to be able to quickly identify high quality, trustworthy clinical practice guidelines, in order to improve decision making for the benefit of their patients.

The case of lung cancer

In a Europe of 500 million people, with all of us potential patients, it may come as a surprise that the biggest cancer killer of all - lung cancer - does not yet have a solid set of screening guidelines across the EU's current 28 Member States.

Yes, the EU has its own study on the benefits of lung-cancer screening because, as one would expect, it recognises that the societal impact of this disease is immense.

And the US has, of late, had a 20% mortality reduction, shown in its National Lung Screening Trial (NLST) results.

As stated, lung cancer is the biggest global killer of all cancers. And fewer than half of newly diagnosed sufferers live beyond a year, with only around 16% surviving for five years.

It is such a huge killer partly because it is harder to detect in its early stages. By the time a person begins to notice symptoms, it has often spread to other parts of the body and is, therefore, difficult to treat.

The majority of lung cancers in both sexes are caused by smoking, but about 15% are not, and the majority of those non-smokers are women, mostly young women.

In the US, the American Cancer Society stated that it had "thoroughly reviewed the subject of lung cancer screening" and issued guidelines that are aimed at doctors and other health care providers.

But it is not just lung cancer (although the Alliance believes that much more could be done in the area of screening). Breast cancer and prostate cancer, for example, are curable in the early stages in many cases.

EAPM argues that, without screening, Europe as a whole and individual Member States will be unable to identify those citizens that could have lung cancer (or any other) disease.

Around one billion people on the planet are regular smokers. We all now know that there is a direct connection in many cases. Non-smokers do get lung cancer, but the risks if you are a smoker are significantly higher.

Undoubtedly, tobacco smoking is the major risk factor for lung cancer, although passive smoking, and a family history of lung, head and neck cancer are, among other factors, also important.

The EU itself has said that, overall, for screening to be cost effective, it has to be applied to the population at risk.

For lung cancer, this is not simply based on age and sex, as n the majority of breast or colon cancer screening. The well-defined risk factors for lung cancer provide the opportunity to target those at high risk and there exist risk-prediction tools that identify those at the highest risk of developing lung cancer.

These citizens clearly have the most to gain.

Jevgeni Ossinovski, Minister of Health, Estonia

The opportunity to introduce precision medicine into lung cancer screening extends further into management of indeterminate findings, such as suspicious nodules. Screening trials have shown how to minimise the clinical implications of these.

Key steps in the implementation of a cost effective lung cancer screening programme in Europe include:

Identification of high risk populations: In Europe we have accumulated sufficient evidence to identify individuals with a high risk of developing lung cancer based on epidemiological modelling and clinical trials.

Cost effectiveness of lung cancer screening: There is evidence from European modelling that lung cancer screening can be cost effective, if one bases this on individuals with specific high-risk profiles in individuals 55-75 years of age, but we are still waiting for the cost effectiveness data from the NELSON trial.

Current evidence on screening intervals: This is based on trials with annual screening and at this time, one would recommend that high risk individuals 55-75 years were screened annually.

However, recent evidence from the NELSON and NLST trials indicates that the EU could potentially work towards precision-based medicine; based on a negative base line screen and first round screen, reduces the risk to 0.4% of the population, thus biennial screening could be considered for this sub-set of individuals.

The lung-cancer community has developed robust guidelines for the management of screen detected nodules, when implemented in an accredited clinical centre.

Resource allocation, which maximises the European Commission's action in enabling lung-cancer screening in Europe, is vital. The lung-cancer screening community in Europe is needs specific funding to assist in the planning for implementation, as well as in supporting future programmes in Europe, through Regional Development funding.

As the EU has stated, each country in Europe will consider the decision to implement lung cancer screening within their own health service mechanisms and procedures. This could be based on the implementation of current screening programmes in breast, colon and cervical cancer.

Congress believes that there should be an EU Council recommendation initiating the work on a EU Expert Group on lung-cancer screening that reflects the experience with the existing recommendations and guidelines for the three other cancers.

And it should leverage on the experience made with the EU actions aiming at harmonising the access for patients to such early detection programmes in the Member States.

It is necessary to formulate a screening-centred strategy involving national decision makers and regulators in the arena of public health, to enable the EU and Member States to contribute to integrating personalised medicine into clinical practice while enabling much-greater access for patients.

Progress in the medical arena is moving at an amazing speed, and wonderful new science is blossoming faster than ever before, nowhere more obviously than in the growing role of personalised medicine.

But we need to be able to make the best use of it, and screening is a major way in which to do so.

Clinical oncology

Congress heard an outline for a workflow for molecular diagnostics in clinical oncology, explaining that it needs to address several aspects in order to be not only reliable but also cost-effective.

Reliability is a fundamental requisite, as the result of the test has to be correct; this goal is reached taking into consideration the analytical aspects.

In this sense, the use of platforms, reagents and protocols that have been labelled as CE/IVD (for diagnostic use) represents for a laboratory director the first choice for implementing a new test

in the routine activity. On the other hand, also the cost-effectiveness should be considered in order to optimise the available resources.

Congress then saw some examples of workflows for molecular diagnostics in clinical oncology in which both aspects had been considered.

One of the key issues for the selection of the appropriate workflow is the clinical request from the oncologist that often require simple and concise information that are informative for a clinical decision for the patient.

Action is necessary at a cooperative and EU level - in gaining new insights into diseases, personalised medicine is already becoming the dominant therapy for cancer and a host of other afflictions.

Quality assurance needs to be further developed to respond to patients requirements. And affordability is the most crucial issue - can we 'afford' to beat cancer?

Personalised Health in Human Disease

Defined as a medical model that proposes the customisation of health care, with medical decisions, practices, or products being tailored to the individual patient, precision medicine is often employed for selecting appropriate and optimal therapies based on the context of a patient's genetic content or other molecular or cellular analysis.

Tools employed in precision medicine can include molecular diagnostics, imaging, and analytics.

Congress heard that the drivers of precision medicine are clear: for patients (and physicians) – more options, durable clinical benefit, reduced exposure to non-effective drugs and potential to leverage current scientific and technological advances; for the pharmaceutical industry – the potential to tackle core challenges in discovering and developing better and more efficacious medicines, to reduce rates of attrition in drug development and to reduce development costs; for healthcare systems and payers – improved efficiency through the provision of effective care and avoiding ineffective treatments.

Our advancing knowledge of disease is outstripping our ability to respond and realise the benefits of these discoveries. Whilst precision medicine is a term used to describe a particular paradigm, it is likely to represent just the next phase of medicine – simply the appreciation of disease diversity.

We are now challenged to develop and deliver therapeutic interventions that cannot be delivered in the broad way they have been in the past.

For example, there is a sense of urgency and a call for action on ***diabetes*** - understanding the disease is key to personalised medicine treating it.

Diabetes is the epidemic of the 21st century - at present, there are 415 million sufferers, with 620m projected by 2040. Treatment requirements are not being met by current methods.

Diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. Insulin is a hormone that regulates blood sugar.

Hyperglycaemia, or raised blood sugar, is a common effect of uncontrolled diabetes and over time leads to serious damage to many of the body's systems, especially the nerves and blood vessels.

It is a major cause of blindness, kidney failure, heart attacks, stroke and lower limb amputation.

In 2015, an estimated 1.6 million deaths were directly caused by diabetes. It is an epidemic of truly global proportions.

Healthy diet, regular physical activity, maintaining a normal body weight and avoiding tobacco use are ways to prevent or delay the onset of type 2 diabetes, for example, and these are clearly lifestyle choices in most cases.

Congress heard that the disease can be treated and its

Christine Chomienne, INCa. Click on the photo for video

Chris Fearne, Malta, and Cristian Busoi, MEP. Click on the photos for videos

consequences avoided or delayed with diet, physical activity, medication and regular screening and treatment for complications.

With 415 million people living with the condition globally, and costing health-care systems about $465bn annually, it's no surprise that much of the healthcare world has its eyes on diabetes and the damaging effect it can have both economically and to the individuals who live with it.

Congress also saw a focus on the personalisation of the treatment of *blood diseases*.

In this context, the personalisation of hematology in general was covered together with the hematology research road map developed by EHA.

In addition, the session discussed the IMI2 HARMONY project which tries to integrate clinical data, informatics and research into the diagnostic and therapeutic algorithm of patients with hematologic diseases.

Many of the diseases in the hematology area fall under the definition of a rare disease. Personalisation, in particular with the new treatments available will cause a considerable financial burden on health systems. Therefore, the political dimension of access to innovative medicines is one of the topics.
The HARMONY project is a European Network of Excellence that captures, integrates, analyses and harmonises Big Data.

The consortium is made up of 51 partners: 44 participants from 10 European countries and seven pharmaceutical companies from EFPIA. It brings together key stakeholders in the clinical, academic, patients, HTA, regulatory, economic, ethical, ICT, and pharmaceutical fields.

HARMONY uses high-quality, multidisciplinary sources to acquire valuable knowledge across the spectrum of haematological malignancies (known as HMs). The goal is to unlock valuable knowledge on HMs.

Figures suggest that healthcare costs for each patient with blood cancers reach twice the figure compared to average cancer costs. This is primarily due to the need for longer time spent in hospital coupled with more complex treatment and diagnosis. The total cost of blood disorders to the European economy was in the region of €23 billion in 2012.

Blood cancers are in the top ten of the most common forms of cancer and are responsible for approximately 100,000 deaths in Europe every year. The proportion of healthcare cost within the total economic burden is higher for malignant blood disorders than for other solid tumours.

There are, therefore, very strong arguments in favour of raising public awareness about the effect of blood disorders in Europe, given that malignant blood disorders represent a leading cause of death, healthcare service use and costs.

Congress heard that key needs include:

- A pan-European approach to the development of new tools to refine HM outcome definitions

And the HI-5 winners are...

EAPM executive director Denis Horgan (back row, left) and co-chair Gordon McVie (front) have Mary Baker (centre left) standing between them. To the right are HI-5 winners, Eelko den Breejen and Ian Walker of Roche, next to Richard Sullivan who presented their award, (all back row), Dr. Elena Garralda of Vall d´Hebron Institute of Oncology (centre), and Marina Gerini of the Lombardy Region. Marina is next to Alexander Eggermont, Institut Gustave Roussy. Photos by Simon Pugh Photography

Olivier Arnaud,, Juvenile Diabetes Research Foundation

● There is a need to establish a clinical data-sharing platform that empowers clinicians, patients and policy stakeholders to improve decision-making procedures and identify appropriate treatments to patients with HMs

● Europe must create a community that reflects the HM landscape made up of key expert academic institutions, national clinical disease networks, and European organisations. This should include the active involvement of patient advocacy groups, clinicians, the pharmaceutical industry, regulatory agencies and other stakeholders

● Provision of tools for analysing complex data sets comprised of different layers of information so that molecular and clinical data can be linked to predict clinical outcomes

● Identifying specific biomarkers, which better define outcome parameters

● Providing a framework for legal, ethical and governance issues

Generally speaking, personalised or precision medicine allows doctors and researchers to predict more accurately which treatment and prevention strategies for a particular disease will work in which groups of people. It is in contrast to a one-size-fits-all approach, in which disease treatment and prevention strategies are developed for the average person, with less consideration for the differences between individuals.

Although the term 'precision medicine' is relatively new, the concept has been a part of health care for many years. For example, a person who needs a blood transfusion is not given blood from a randomly selected donor; instead, the donor's blood type is matched to the recipient to reduce the risk of complications.

While examples can be found in several areas of medicine, the role of precision medicine in day-to-day healthcare is relatively limited. Researchers hope that this approach will expand to many areas of health and healthcare in coming years.

There is a growing body of troubling evidence about the lived experience of those involved in stratified medicine, both patients and staff.

The promise of personalisation has been heralded for some time. We want to pay attention to the effect that pursuing this promise has had on people's lives in order to improve the quality of care provided to patients and staff.

Meanwhile, Congress heard that the battle against ***eye disease*** in Europe needs to be fought at EU level. There are some 39 million blind people in the world, but 80 per cent of blindness can be cured or prevented. That's 31.2 million people who are blind when they needn't be.

Key aims are:

● More timely diagnosis, intervention and, at the core, research and awareness of the extent of the problem are key

● Research into the causes of cataracts and other eye diseases needs boosting across the EU, with platforms put in place for effective collaboration between academia, industry and healthcare systems

● There is a definite case for more screening programmes for preventable blindness, coupled with a need for agreement and coordination across the European Union's Member States on this

Meanwhile, Congress heard that ***prostate cancer*** is the second-leading cause of cancer, and accounts for almost one-in-ten cancer deaths among European males. There is an ongoing debate of the benefits of screening, meanwhile, that needs resolving and acting upon swiftly.

Given the EU's ageing population, the burden on society due to prostate cancer is expected to increase dramatically. In this context, it is perhaps surprising that the research funding available is below other killer cancers. This means that progress in the area is slow.

A further issue is that EU Member States have large disparities in how often prostate cancer happens, and the survival rates vary alarmingly from country-to-country.

Christine Chomienne, INCa

Given the amount of medical data theoretically available, in the case of prostate cancer there is not enough information on risk factors or patient characteristics. Arguably, the data is out there, as is the genetic information, but it is not being used in the most efficient ways possible.

So, knowing which patients are safe in the short term, and which will have the best outcomes via targeted treatment, is a lot harder than it should be. As with many modern-day healthcare breakthroughs, new knowledge is taking too long to be put to effective use on the ground.

Such inefficiency has an obvious effect on safety and on economics, too.

The above issues and challenges can only be solved by key stakeholders, including patients, coming together and collaborating.

Prostate cancer incidence is set to rise and Congress heard that we have to act now, every stakeholder. There is no time to be lost, but we need agreed guidelines.

Key points include:

- Guidelines (on screening and more) may well be the way forward, given that they potentially have less rigidity and therefore more flexibility (within strict standards of safety and ethics)

- Innovation has brought about a greater need for adaptation through appropriate frameworks that must be designed by experts, in consensus - albeit with necessary input from regulatory bodies

- It is vital to ensure that any and all agreed standards can be met down the line. These include ethical considerations, patient safety, certainty within timeframes and facilitation of advancements for the benefit of Europe's patients and society in general

- Screening needs to be continuously reassessed, with guidelines updated when applicable. Despite arguments of over-treatment and issues of cost, it is one of the most potent preventative tools available to us today

"""""""""""""""""Quotes from Congress""""""""""""""""""

"Tapping into knowledge repositories to make full use of it for the benefit of patients is mainly a question of architecture. We need interoperable eHealth systems to gather, filter, analyse, and use Europe's health data, in full respect of patients' consent."

Vytenis Andriukaitis,
European Commissioner for Health and Food Safety

"There has been an issue between the pharmaceutical industry and Member States when it comes to the pricing of medicines. The Member States' buyers need to come together so that real progress can be made on pricing policy."

Chris Fearne
Minister for Health, Malta

"Our most significant milestone has been the overhaul of our infrastructure to better reflect and adapt to the paradigm shift that is occurring in clinical research."

Alexander Eggermont, Director General,
Institute Gustave Roussy, Paris, France

"It is clear that we need to engage in respect of personalised medicine at all political levels. The Alliance will do this in its role as a platform for all stakeholders in the arena of personalised medicine."

Denis Horgan,
EAPM Executive Director

A message from Vytenis Andriukaitis
European Commissioner for Health and Food Safety

Whilst we have many similarities in our DNA, there are considerable genetic variations that make each one of us unique. With today's technological advances, it is fast becoming a global imperative to ensure that medicines are tailored to our specific physiology and needs.

As a medical doctor, I am convinced that personalised medicine holds huge potential for patients, offering better targeted treatment, avoiding medical errors, and reducing adverse reactions to medicines. More research is needed for its successful uptake in our health systems, and a key element in making this happen is to maximise the possibilities of big data in health1.

Big data has enormous potential to advance medical research, bring about greater innovation in healthcare, and improve the overall performance of health systems. However, there are a number of barriers to fully capturing and making full use of the considerable health data we have in the EU, notably fragmentation of data sets and insufficient computing infrastructure to connect Europe's eHealth systems.

We are working together at the EU level to remove these obstacles so that we can help get innovative medicines to patients faster and improve our health systems.

Tapping into knowledge repositories to make full use of it for the benefit of patients is mainly a question of architecture. We need interoperable eHealth systems to gather, filter, analyse, and use Europe's health data, in full respect of patients' consent.

"""""""""""""""""Quotes from the sessions""""""""""""""""""

"Europe needs to set a timeline for implementing lung cancer screening."

John Field,
University of Liverpool

"The basket and umbrella trials do not have the necessary flexibility to ensure rapid translation to the clinic for the benefit of patient."

Gennaro Ciliberto,
Instituto Nazionale Tumori

"The purpose of our guidelines is to harmonise care and improve outcomes for patients. He have the opportunity to do this across the EU."

James N'Dow,
EAU

"By sharing data we will come faster to finding the link between a genome and a person's condition so that we can have the best diagnosis, prevention and treatment."

Christine Chomienne,
INCa

"One of the solutions to mitigate concerns and risks as regards the misuse of genetic data lays in the adoption of non-discrimination laws."

Denis Horgan,
EAPM Executive Director

"The way we put drugs onto the market will no longer be efficient in the future. Business models need to adapt to a new reality."

Peter Keeling,
Diaceutics

The researcher's story

TM is a 34-year-old researcher living and working in Germany. After almost two years spent working in a particular area of genetic research he discovered that almost exactly the same work was being undertaken at a university in another EU Member State.

TM told EAPM that, while his work still obviously has considerable value, he feels that time has been wasted in both countries due to duplication.

There is a need, he says, for a great deal more coordination and collaboration on a pan-European level.

He added: "I'm pretty sure that my case is not unique. In fact, I'm certain that this kind of needless repetition is occurring everywhere across Europe as the right hand doesn't know what the left hand is doing. This is unacceptable in an area as important as public health and has to improve quickly."

Gordon McVie, EAPM Co-chair

"""""""""""""""""Quotes from Congress""""""""""""""""""

"There is a sense of urgency and a call for action on diabetes - understanding the disease is key to personalised medicine treating it."

Desmond Schatz MD
University of Florida Diabetes Institute

"We must look at how to realise the promise of the patient-centred approach. Better methods of treatment and treatment education need to help the person at the level of the person."

Mark Lawler
Queen's University Belfast

"Technology advancements do not know borders, so countries must work together, share knowledge and experience."

Simon Harris
Minister of Health, Republic of Ireland

"It is important to highlight that personalised medicine will have to become available to all, and not just to the priviliged elite."

Marian Harkin
MEP

Belfast: Painting pictures of our host city

All photos by Simon Pugh Photography

European Alliance for Personalised Medicine

Alexander Eggermont, Institut Gustave Roussy

Lorraine Nolan. Click on the photo below for video

European Alliance for Personalised Medicine

Quotes from the sessions

"The Canadian Institutes of Health Research are glad to contribute to this event in order to strengthen the links between Canada and Europe in the area of personalised medicine."

Etienne Richer,
CIHR Institute of Genetics

"Pilot data from qualitative interviews suggest some problems of burnout and distress affecting the ethos of some trials."

Joshua Hordern,
University of Oxford

"Society is living longer, it is an incredible achievement, but in the wake of this achievement come challenges, and I believe precision medicine can really lead to a healthier world."

Mary Baker,
Past President European Brain Council

"One of the solutions to mitigate concerns and risks as regards the misuse of genetic data lays in the adoption of non-discrimination laws."

Denis Horgan,
EAPM Executive Director

"We need large data sets and data sharing in order to detect biomarkers that predict response to treatment."

Fabien Calvo
Cancer Core Europe

"The EU-AIMS Project will be the first biological EU-led randomised trial in autism"

Declan Murphy,
Kings College London

The nurse's story

A 49-year-old nurse KP, who lives and works in Poland, says that one of the worst aspects of her job - which she generally loves - is having to explain to her patients in hospital that providing access to clinical trials is difficult and providing the most modern medicines is often impossible due to a lack of resources.

"It is very frustrating and often confusing for a patient. They cannot understand why they are being denied a particular treatment, even though they may know about it - or their families may know about it - through the mainstream media or the internet," she told EAPM.

"We strive to make all necessary decisions together, but sometimes the options just don't really exist."

Declan Murphy, of King's College London, (above) joined Barbara Baggiani, Silicon Biosystems, in the session on innovation

Alastair Kent, Genetic Alliance UK, and Kaisa Immonen, of the European Patient Forum, addressing attendees on Wednesday

Quotes from the sessions

"We need to build bridges between genomics and medicine so that the shilft between research to practicing medicine can become a reality."

Ewan Birney,
European Bioinformatics Institute

"Citizens and patients will be key players of Big Data. They are the first aggregators of data and must therefore participate in scientific research. It goes beyond the question of consent."

Ernst Hafen,
ETH Zurich

“Too often, regulatory agencies, governments, and funding agencies do not stimulate the integration of research into care and vice versa."

Denis Lacombe, Director General,
European Organisation for Research and Treatment of Cancer

"One of the main challenges that arises when it comes to the manufacturing of precision medicines, is the location of the production."

Killian O'Driscoll ,
NIBRT, Dublin

"Research should be carried out 'with' or 'by' members of the public, not 'on' or about them."

Mairead O'Driscoll,
Health Research Board of Ireland,
IC-PerMed

Patient story - rare cancer

A 53-year old patient, MD, living in Luxembourg, told EAPM in the run-up to this Congress that she is optimistic that healthcare is moving in the right direction.

This was partly based on the fact that her 29-year-old son recently took advantage of cross-border treatment when suffering from a rare cancer, and this came about through long and fruitful discussions with healthcare professionals resulting in shared decision making.

The results so far, MD says, were well worth the time that she herself had to take off work and the travel involved.

The Luxembourger also feels that different, and more modern, models for clinical trials helped in her son’s case (as there are, by definition, fewer rare cancer sufferers) and that revisions to data protection laws will mean that her son’s health data should be available to help researchers and, ultimately, other patients down the line.

Banner headlines: EAPM makes a splash outside the Waterfront congress venue in Belfast

Big Data for Better Health

Big Data is here and here to stay. We are sharing more and more information in more and more different ways and the trick, clearly, is how to use these data superhighways for the benefit of mankind.

It is clear that patients, researchers and industry all need information. And there's no doubt that there are ever-more new ways of collecting it.

Clinical trials, screening programmes and the subsequent sharing of related data across borders is crucial. Yet data needs not only to be shared but the knowledge to interpret it must be increased.

There is a wealth of data out there now, more than ever before and growing by the day. EAPM believes that we must remember that, in health, this information should revolve around, and give benefit to, the patient.

In respect of personalised medicine, Big Data represents the vast and continuously growing amount of health information (including biomedical and environmental) and its usage to drive innovation in translational research and health outcomes tailored to the individual.

Using these data to first understand the cause of disease, the medical profession can then develop new drugs and therapies to find the cure, 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.

Not only does Big Data offer the potential to revolutionise the effectiveness of health interventions, it may also help ensure the more effective management of resources in what are increasingly cash-strapped public healthcare systems.

Big data in healthcare is being used to predict epidemics, cure disease, improve quality of life and avoid preventable deaths.

With the world's population increasing and everyone living longer, models of treatment delivery are rapidly changing, and many of the decisions behind those changes are being driven by data.

The drive now is to understand as much about a patient as possible, as early in their life as possible - hopefully picking up warning signs of serious illness at an early enough stage that treatment is far more simple (and less expensive) than if it had not been spotted until later.

Concerning the regulation of medicines in the EU, which is an integral part of personalised medicine, Congress heard that much has changed in the regulatory mindset - regulators are working to ensure that they stay abreast of the latest innovations.

New regulations should therefore be good news. The European Commission has adopted a directive in order to pave the way for a pan-European research area. The principle is fine, the implementation is the problem.

There is still much to do, particularly concerning policy, and the regulation and implementation of science, and this is where Big Data truly comes into its own.

We have more than enough data in the medical world, but we don't share enough of this data. We must align stakeholders' interests with our common goal, namely the very best health care that can be provided.

Congress heard that the implementation of science is frequently like a post-code lottery, as to whether patients will receive the correct tests or not.

An individual's control over his or her personal health data will

James N' Dow, chairman of the Guidelines Office Board at the European Association of Urology in the Netherlands.

Eelko den Breejen of Roche, and Sue Hill of the NHS

Peter Meeus of Shire

be a key asset for better and more effective healthcare, and the growth of big data posits legal, ethical and societal issues about health data ownership.

It is very important to find commercial models permitting owners, not third parties, to benefit from personal data assets.

Core aims include:

- The integration of personalised medicine into clinical practice will be enabled through scientific evidence generated by multiple data

- Complex data protection rules are a major regulatory constraint and an impediment to biomedical progress toward achieving personalised medicine. Updating these EU rules should take account of the impacts for individual's health and global healthcare

- Changes are needed in the way data are collected. New technologies are revolutionising the possibilities for capturing data. The use of electronic medical record data as a source of readily available research data eliminates the need for costly and lengthy active new recruitment of trial subjects, and drastically reduces collection of redundant specimen and data

- In order to allow integration of information from multiple sources, the data must be well characterised, standardised, and compatible

Personalised Health and the Policy Agenda

The European Union has, as one of its core values, the central ideal of equality and a strong way to measure success in this goal is through the well-being of all citizens.

There are many challenges to providing the best available healthcare for every citizen, not least in the rapidly developing arena of personalised medicine, and the ageing population (ironically living longer due to generally better drugs and diets) is putting a huge burden on what are currently unsustainable healthcare systems.

Time is running out for Europe to 'get healthcare right'. For example, the key ingredient of innovation needs momentum, collaboration between stakeholders needs to increase on a grand scale, and education of policymakers, the public and healthcare professionals needs to get up-to-speed.

It is one of the European Union's goals to create an internal market of goods and services and, when this is applied to healthcare, it can grate with some Member States, given that the latter have competence for the healthcare of their own citizens.

But, as time goes by, health policymakers in the EU will increasingly have to take into account how the bloc's laws (and the rulings of the European Court of Justice, or ECJ) will affect their management of healthcare systems. This is especially because ECJ decisions have undoubtedly changed the healthcare opportunities for patients.

We live in a fast-changing world. But one could argue that some of the changes only actually happen quickly in certain sectors of our society.

Take data gathering, storage and exchange - speedier and more efficient than it has ever been. But while it works to a very high level in, say, the finance and security sectors, it has yet to be properly transposed into daily healthcare across the EU.

Perhaps there simply isn't the political will. This despite the fact that most residents of Europe have been shown to put health high on their list of priorities. Yet, how many politicians put health high on the agenda during their campaigning? Very few, one would suspect.

This is strange, to say the least because not only does the ageing population care about health, these patients and potential patients want more-and-more to be placed at the centre of their own healthcare decisions and want access to the best treatments available.

There are many and varied reasons to explain why patient access is being delayed, blocked and made inequitable. For example, despite the speed at which science is moving, the 'system' of getting efficacious drugs affordably to those who need them across Member States is patently not fit for purpose.

Politicians and those implementing legislation need to step up

Peter Keeling, of Diaceutics, spoke in the session 'Research Frontiers in Personalised Medicine"

to the plate and ensure that this is no longer the case.

During the Luxembourg Presidency of the EU at the end of 2015, the European Council issued its conclusions on personalised medicine and access to it for patients, highlighting how 'the development of personalised medicine may offer new opportunities for the treatment of patients in the European Union'.

Happily, earlier this year, the European Commission presented its Communication "*Establishing a European Pillar of Social Rights*".

This Pillar is meant to be guidance for what has been called "a renewed process of upward convergence towards better working and living conditions in Europe".

Its stated aim is to deliver new and more effective rights for citizens. The Pillar is applicable to all EU Member States wishing to be part of it, and is not directly enforceable. It would need to be turned "into dedicated actions and/or separate pieces of legislation".

The Commission suggested that where needed, "existing EU law should be updated and complemented, while fully respecting the Member States' competences and taking into account the diversity of their situations".

Part of this initiative is the issue of healthcare across the Union - which as we know is a Member State competence. And, of the 20 principles that form the core of the Pillar, the Maltese Presidency of the EU stated at the time that it wished "to draw the attention to the principle that reads: Everyone has the right to timely access to affordable, preventive and curative healthcare of good quality".

This is a basic EU premise, of course.

In one of several staff working documents accompanying the communication, it's clarified that: "The Pillar sets out a general right of access to good quality preventive healthcare and medical treatment. It goes beyond Article 35 of the Charter in that it requires timely access to healthcare and stipulates that it should be affordable and of good quality."

Those two magic words, 'timely access', mean that all 500 million citizens across the EU's current 28 Member States should be able to access healthcare whenever necessary. What is required, it is argued, is a "balanced geographical location of healthcare facilities and health professionals, as well as policies to minimise long waiting periods".

Affordable healthcare implies that citizens should not be prevented from necessary care simply because of cost. Furthermore, this part of the Pillar includes the right to healthcare of good quality - essentially, healthcare should be "relevant, appropriate, safe and effective".

This is not too far a step away from the aims of advocates of personalised medicine, such as EAPM, who have consistently

Mairead O'Driscoll, , Health Research Board of Ireland, IC-PerMed

called for the right treatment for the right patient at the right time while attempting to tackle topics such as equitable and speedy access to the best medicines and treatments available, regardless of location or income.

A further breakdown of the Pillar, states that preventive and curative healthcare means "access to medical treatment and public health services, including health promotion and disease prevention".

Again, those pushing for better-targeted treatment have always argued in this direction and continue to do so.

The European Council has been asked to consider whether it provides sufficient guidance for upward convergence of national health systems, as well as what the implications of establishing at EU level a commitment to provide timely access to affordable, preventive and curative healthcare of good quality are.

From a broader perspective, citizens' rights are those protections offered to all citizens of the EU. These include free movement and the right to residence, as well as equal treatment under EU laws in areas such as work, education, social security and, particularly important for us, health.

It is clear that there are already inequalities right across Member States, and often within the regions of some of them, especially when it comes to access for patients to the best treatments available.

Cross-border cooperation in many fields is sub-optimal, given the afore-mentioned Member State competence for health. Yet Europe has played its part in health and healthcare.

Let's take the ECJ as mentioned above and the important issue of cross-border healthcare. The latter is now a right for citizens of the European Union. Its implementation has, admittedly, been patchy to say the least but the legal entitlement for EU citizens to seek healthcare within the soon-to-be 27 Member States has been enshrined.

The rights of citizens to 'well-being' are not only a tenet of the EU and a moral duty for society, they are also now, as noted, part of the rulings of the ECJ, whose work over the past three decades essentially led to the landmark Cross-border Health Directive.

Key points from that directive are that it clarified the rights of patients to seek healthcare in another Member State and is aimed at simplifying their application in practice.

It legally ensures that patients are allowed to receive treatment in another EU country and be reimbursed. And it legally guarantees fair and quick procedures, including for the actual reimbursement of costs.

Moreover, it guarantees patients access to their medical records and also that the protection of their personal data will be guaranteed in the cross-border healthcare setting.

On top of this, the directive makes it the law that if something goes wrong, patients will be guaranteed redress and compensation and will be provided with assistance by national contact points for cross-border healthcare.

In theory, the ECJ has a legal right to intervene if the directive is not being followed.

It is clear that patients need frameworks and good systems to augment and even bring about their empowerment. These can be legal, organisational, political and so on. Multi-stakeholders each have a part to play.

As suggested above the ECJ has at times produced rulings in respect of cross-border healthcare. These rulings have, in turn, brought about changes of a legislative or administrative nature in certain EU countries.

These include, for example, the Czech Republic, France, Germany, Poland, Sweden, Spain and the UK.

It is safe to assume that there may be trouble ahead for British

Quotes from the sessions

"Security should not be about preventing health data from being effectively used, but about making good use of those data in a secure way."

Jevgeni Ossinovski,
Minister of Health, Estonia

"Personalised medicine is going to change public health practices whether we like it or not! So we'd better get prepared now."

Natasha Azzopardi Muscat,
Health Information and Research, Malta

"We need a cross-sector collaborative approach to develop healthcare for all, including academia, research and industry to maximise the development and potential of genomic medicine."

Sue Hill,
CSO, NHS

"The Governement issued today the UK Industrial Strategy where genomics is singled out as an important vehicle of growth. This is a good day for genomics."

Sir John Chisholm,
Genomics England

"One of the greatest challenges we have to tackle is the way we manage cross-border data sharing."

Bogi Eliasen,
Copenhagen Institute for Future Studies

"Cultural gaps are holding back translation of research outputs into marketable products."

Richard Barker,
CASMI, Oxford

Patient story - pancreatic cancer

Londoner Tom, aged 48, ignored what turned out to be early symptoms of abdominal pain and weight loss, as they did not clearly point to pancreatic cancer. He later developed jaundice, however.

It became clear to Tom that one of the major issues with the disease is that the symptoms can often be vague, and that by the time a patient is diagnosed the cancer may have spread to other organs and even into bones.

This was the case with Tom and, before he died, he was adamant that there needs to be more dedicated support and information available for people with the disease.

Denis Lacombe, EORTC

citizens in this area should future rulings of the court be set aside in a post-Brexit world.

Generally speaking, in recent years, patient mobility within the bloc has increased, but it is still very low (representing in the region of just 1% of overall public expenditure on healthcare). However, as a result of ECJ decisions, patient rights to treatment have been extended, coupled with an increase in awareness of such rights.

Such ECJ decisions have influenced access to cross-border healthcare (as well as reimbursement schemes) for hospital and non-hospital care to which a citizen is entitled in his or her own Member State.

The EU, despite key legislation in areas such as IVDs, clinical trials and data protection, still does not have an over-arching EU-wide structure and legal framework for health.

Fortunately, the ECJ plays an important role in attempting to fill that gap but, in the case of healthcare, we surely need 'more Europe' rather than less.

Engagement and regulation in the PM era

Congress placed a focus on ways to bring policy, legislation, guidelines and regulations up-to-speed in the face of rapid changes in the way health is being delivered across the EU.

Problems with implementation and compliance in terms of regulations on, for instance, screening, plus issues with data collection, storage and sharing, as well as a need for better cooperation and collaboration among stakeholders and legislators, are hindering the adoption of a more-targeted approach in Europe's healthcare systems.

EAPM has already called for urgent, consensus-driven action taking into account the differences between Member State resources, and their ability and willingness to implement guidelines that could save the lives of many of their citizens now and into the future.

Congress heard that evidence-based best-practice recommendations are not disseminated effectively. Clearly, when knowledge is not actively transferred variations in clinical practice will continue.

Where variations in practice occur, healthcare is unequal within individual countries and across EU member states, and health systems are likely to be inefficient.

If all stakeholders, including patients, are not meaningfully included in decisions on which research areas should be prioritised, what outcomes are of the highest importance, or what and how recommendations are made, then they are denied the choice of informed shared decision making.

Legislators need to keep a close eye on development and needs in the health field, so as to ensure both adequate protection but, crucially, still allow and actively encourage the free-flowing exchange of information that is absolutely vital for research and development.

A key point that emerged is that, in these days of innovation, EU Recommendations need to be regularly updated to take these new methods of treatment properly into account, as well as stronger action to ensure that Member States implement them correctly and quickly.

Another key issue is that there is insufficient collaboration between all stakeholders currently operating within their own 'silos'. This is a major problem in many areas of health generally, and personalised medicine in particular, covering everything from education to information sharing, and from authorities deciding patient access to the need for one, clear voice to communicate with legislators and much more.

There are now mentions of health in official EU documents – but they all continue to emphasise the strict limitations. As one EU legislative summary makes clear, "The EU does not define health policies, nor the organisation and provision of health services and medical care." The EU's role is only "to complement national policies."

In addition, the various strands of health-related policy are split widely across the EU's institutions: the ministerial health council is no more than a subsidiary of the employment and social affairs council (and does not even enjoy direct input into the reflections of EU finance and economy ministers); within the Commission, departments (and their commissioners) covering research, enterprise, digital technology, trade, or social or regional affairs each have their own health fief, alongside the health department, which has no hierarchical position of oversight; and in the European Parliament, health is similarly split between committees on consumer protection, research, industry, social affairs and so on.

Panel for the session on Big Data

Good decision-making in such a scenario would be challenging even in relatively simple matters. But the highly complex area of personalised medicine finds itself buffeted by a regulatory tempest as it attempts to emerge from its chrysalis.

Research and the Innovation Agenda

Trying to bring innovation into healthcare systems by dealing with just the fragments of the problem runs into challenges. The barriers to market access are not individual problems. They are the sum of all the individual problems. And the only way to tackle that is by addressing the system as a whole.

Research should be the key driver in personalised medicine, Congress heard. We must bring personalised medicine to the citizens of Europe.

Research should be all about pairing therapies with diagnostics. We all have friends and relatives who have been or are patients - they've probably been subjected to a type of medicine that has been a little tested and then used to treat everyone broadly the same.

That has benefited us over the years in the evolution of treatment but more recently, with a technology revolution going on, genetics, and other types of testing, we are really able now to find much better types of patients in the same disease.

The pharmaceutical industry has been able to laser-focus treatments on those different types of disease.

As far as research is concerned, the possible next steps in the value of treatment project - such as exploring the application of the developed methodology to other disease areas e.g. rare diseases or chronic pain - as well as a future focus on interventions such as rehabilitation, is essential.

Research frontiers in personalised medicine were there to be exceeded and surpassed - and that the future held much in terms of discovery and progress.

Europe can be pragmatic in its policy formation - which can provide the space for integrating innovation. Even Europe's oft-criticised caution on transferring data can be interpreted more positively as a demonstration that the EU is a strong defender of international data security - something appreciated by both stakeholders and investors.

And the intricate patchwork of its regions that can sometimes impede standardisation has the merit of offering a series of testing grounds for different approaches to problem-solving.

There is so much to be gained by working together, whatever reservations may persist are eventually likely to be overcome.

Congress heard that it's not enough to see bringing innovation to the market as a linear process.

For many healthcare innovations, the classic process just doesn't apply. It's no longer a phased exercise that leads from research and development to regulatory approval, and then to health technology assessment and on to the final reimbursement decision.

Congress heard that the inherent uncertainties of innovation demand more agile pathways that can take into account the evolving knowledge of a product's characteristics. Otherwise the promise of the innovation may not be realised at all.

Much of healthcare innovation now turns on identifying therapeutic targets and the use of paired diagnostic companions with novel molecules. The resulting optimisation of care, the increased efficiency and decrease in adverse events, and the reduced cost and waste resulting from more selective and rapid clinical studies are all welcome.

In other words, detailed adjustment of one or another parameter – such as a budgetary cap, or conditional marketing authorisation conditions, or additional opportunities for early dialogue with HTA bodies – are not going to suffice. It's a change in the concept of coping with healthcare innovation that is needed, a recognition that to solve the individual issues, an approach must be found to embrace the challenge of innovation as a whole.

The approach has to be not only more holistic, but also able to operate at a different pace. New technologies must be allowed access to healthcare systems at a faster rate than is the current norm. Otherwise they will perish.

Across Europe's complex landscape for healthcare regulation, the responses so far have been fragmented, and at European Union level they remain administrative or technical rather than political.

Greater engagement at political level will be necessary in

Peter Sterk, University of Amsterdam

Europe to ensure the framework is conducive to innovation – and not just to today's innovation, but to the innovations that will emerge in the coming decade.

Europe's and the international research landscape remains too fragmented. A lack of critical mass in many research centres means not enough patients, biological materials, technological resources or competences.

Wider collaboration and better infrastructure would help: technical platforms for genomics and other specialty disciplines, screening facilities for new pharmaceutical agents, biobanks for tissues and biofluids, plus quality-assured patient registries.

So too would better resources, for prospective validation of biomarkers that may be predictive for treatment, networks on biostatistics, epidemiology and outcomes research.

Integration along the research continuum would make it easier to bridge basic/preclinical research and clinical research in early translational research.

Core aims include:

- Research needs to be structured to emphasise the key position of the patient in personalised medicine

- Research needs to span over the entire translational chain. Healthcare professionals need to be able to translate research into clinical practice and bring it forward to public health decision makers

- There is a need for a cross-sectoral research involving pre-clinical, clinical work, academia, industry and patients, to be completed by real world data

- Patients have to be involved from the very beginning of research projects

- New forms of collaboration are required between academic centres, the pharmaceutical industry, regulators and payers

- Open research collaboration mechanisms are required for translation from basic research to clinical research, including access to data and diagnostics which allow patient stratification

Value

Congress heard that one of the biggest changes in the context for healthcare in recent years has been the new emphasis on cost.

For decades, healthcare spending rose steadily in the developed world, in line with the growing prosperity that permitted many countries to continue funding wider coverage of the new diagnostic and treatment regimens that medical science offered.

But certain factors have radically modified that equation in the last decade, giving new prominence to getting the full picture of the value of treatment.

The most obvious new factor is the ageing of the population. Now the burden on health and social security spending is greater than ever before because people are living longer - thanks in many cases to the advances in healthcare.

They are living longer, but also suffering more disease, and for longer, with consequent strains on the resources to supply care. The skewed distribution of healthcare demand is well known, with the vast majority of spending concentrated in the final years of life as health declines, and as co-morbidities and acute and often sustained interventions proliferate

On the threshold of the third decade of this new century, society and its appointed leaders, faced with numerous new and valuable, but often costly, diagnostic and therapeutic options, are recognising that new treatments are worth a lot, but are inevitably posing the question of just how much they are worth.

The question is obvious, but finding answers to it is not so easy.

Poster people: Abstracts at Belfast Congress

Wednesday night saw Denis Horgan name five winners of the posters/abstract awards. The winners were Francesca Amoroso (CCRB at Queen's University Belfast), Matthew Alderdice, also of QUB, Diaceutics, Richard Gallon and Laura Le Gall, of Ulster University. Denis is pictured centre left and bottom left with Matthew and Richard respectively.

European Alliance for Personalised Medicine

Carin Smand, European Hematology Association

General conclusions

Do we, as a society, have the capacity to tackle the big questions raised by Congress adequately? Do frameworks exist to cope with the inevitable scale and complexity of such issues?

Are they apt to cope with the speed of evolution that sees the EU currently under the presidency of a country that was part of the Soviet bloc a generation ago – and a country that is leading Europe on digital technology, too?

Certainly, in terms of healthcare, Europe is currently not displaying the boldness that would enable it to grasp success from what looks like getting closer and closer to the jaws of failure.

A clock is remorselessly ticking as Europe merely toys with the edges of the multiple challenges of the ever-rising demands for care, ever more fragile resources, and the manifest inequalities in opportunity, access and outcome across Europe's countries, regions and social groups.

The EU lacks a framework for collective reflection, decision-making and action in healthcare.

Consequently the problems proliferate, and more and more of them go unsolved, and the opportunities for solving them are overlooked.

Without a change in mindset, an openness among all stakeholders to working together to systematically identify nd deploy the best available solutions, the prospects for the health of Europeans are grim.Amid all the European Union's official 2017 reflections on what it should be doing in the years ahead, improved mechanisms for collaboration have been conspicuously missing.

The notion of sovereignty has been largely neglected in discussions initiated by the European Commission's paper on The Future of Europe.

The options it sets out are timid in this respect; they simply do not go far enough to provoke a radical review. As a result they do not penetrate to the heart of the weaknesses of EU governance - the uncompromising attachment to the local and partial view, the persistent failure to perceive the bigger picture, and the consequent inability to conceive solutions that are equal to the challenges Europe faces.

But if solutions are to be found, the EU is unquestionably where the search should be concentrated.

What the EU needs is a framework that can shift its approach to healthcare so that it promotes rather than restricts access to the benefits of innovation and of innovative thinking.

This would be a new form of partnership in which all stakeholders are engaged and all can find their place as contributors towards a shared goal.

A Note on the Future

EAPM is supporting the goal of bringing innovation into healthcare systems at the regional, national and EU levels.

It is doing this from a multidisciplinary citizen/patients-based approach, while working closely with the European Union institutions and Europe-wide regulators.

The document notes that a massive improvement in the health of Europe's citizens is theoretically within reach. Scientists, technologists, physicians and health economists have devised innovative pathways to boost the health status of individuals and to make healthcare systems more sustainable through personalised health and medicine.

What is needed to turn this vision into reality is a clearer understanding among Europe's policymakers and decision-takers that a paradigm shift is required, with new forms of cooperation, collaboration and awareness across multiple domains and stakeholders.

EAPM is promoting that understanding, with the ambition of seeing personalised health delivering major benefits by 2025 through coherent strategies based around prevention, early detection, and treatment.

A healthier Europe will mean citizens spending less and less

Ernst Hafen, ETH Zurich

Ewan Birney, European Bioinformatics Institute

time in hospitals under expensive treatment regimes, often at a direct cost to the taxpayer, and it will also mean that people receiving the right treatment at the right time are more able to stay in the workplace, thus generating wealth rather than whittling it away.

By the same token, a move towards preventative medicine will reduce costs still further. A focus on research into new medicines, innovation and cutting-edge treatments will also create jobs – whether they be in research itself, education, design and manufacture of in-vitro products or within the pharmaceutical industry.

Among the barriers to integrating innovation into the lives of the European Union's citizens are a lack of education and awareness, a need for greater patient empowerment, the recognition of the value of personalised medicine, the collection, storage and sharing of vital research data, and problems with access to care.

Yet with the backing of the European Union, we can work towards building a healthy and wealthy Europe, one worthy of the EU's stated goals.

Key points in our document '*From here to 2025: personalised medicine and healthcare for an immediate future*' include:

- Investments, in education across all stakeholder groups, and in access – to testing and to therapies

- Policy priorities include the development of genomic profiling (particularly through its Million European Genomes Alliance)

- Incentives to drive wider and earlier access to diagnosis and the necessary engagement among all stakeholders, and conducive regulatory frameworks

- Ensuring that personalised health does not become the preserve of elites: systems must be found to ensure that innovation is rewarded but that there is wide and equal access to the fruits of innovation, while the overall costs are contained

Read the full document *here*

European Alliance for Personalised Medicine

EAPM

6th Annual Conference

BRUSSELS

Plans for the sixth annual Presidency conference of the Brussels-based European Alliance for Personalised Medicine are already in place for 27-28 March 2018.

The 'Personalised Medicine and the Big Data Challenge' event will be held under the Bulgarian Presidency of the EU, which runs from 1 January to 30 June.

Taking place close to the Brussels seat of the European Parliament, the conference will feature plenary sessions in the afternoon of Day One, followed by a dinner in the parliament that evening and a day-long event on Day Two.

The conference will revisit the prestigious Bibliothèque Solvay in Parc Leopold.

The effect on healthcare of Big Data, across many disciplines, will certainly mean that clinical researchers and other healthcare stakeholders and professionals will need to develop new expertise and a different approach. Ongoing training will be vital, but there are many other issues to be discussed.

Given the European Parliament elections, which will be not much more than a year away at the time of the conference, a key goal will be to raise awareness of personalised medicine in respect of current MEPs who will be standing again, and potential new Members.

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

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

Belfast Congress: A sign of the times

Top: Cristian Busoi; centre (left to right) Mueen Sharaf , Sebastian Schmidt; bottom Mark Lawler, Ivana Cattaneo & Emanuele Ostuni.
Photos by Simon Pugh Photography

Richard Barker, Centre for the Advancement of Sustainable Medical Innovation

EAPM Annual General Meeting

During Congress the Alliance held its Annual General Meeting in the boardroom at the Waterfront venue.Joining the board is Dr. Jasmina Koeva-Balabanova, founder and chair of the Bulgarian Alliance for Precision and Personalized Medicine (BAPPM).

The meeting also confirmed the venue and dates of the second EAPM annual Congress (see below). In the interim, the Alliance will place a key focus on prevention, screening and early diagnosis, while continuing its SMART Outreach programme to take in the cities of Berlin, Paris and Vienna among others.

Coming up in 2018

EAPM has several key events and programmes planned for next year and hopes to have the ongoing support from our valued sponsors and contributors.

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Milan, MEGA and more...

Similarly to the inaugural 2017 Congress in Belfast, te second Congress in Milan will be a pan-European, multi-disciplinary event specific to the fast-moving field of personalised medicine and will take place from 26-28 November 2018.

A key aim of the Congress is to allow cross-fertilisation between the different disease and policy areas, allowing delegates to gain a greater depth of knowledge into barriers in the field of personalised medicine.

It is also geared towards offering up valuable evidence and stakeholder opinion on which policy makers can base their decision making on how better to integrate personalised medicine into EU healthcare services.

Once again Congress will bring together the different streams (including scientists, industry, regulators, patients and more) in order to allow decision makers to understand changes that are required, now and down the line.

2018 will see further progress on the Million European Genomes Alliance - dubbed the MEGA project - which is aimed at linking gene sequencing efforts across the European Union.

MEGA's goal is ultimately to compile a database of a million genomes for clinical research purposes, using a coalition of the willing Member States, as well as for stimulating the life sciences.

Videos from Belfast

EAPM and eCancer recorded many video interviews in Belfast, some of which you can view by clicking on the photos on Pages 14. and 22. For others, please follow these links:

Guillermo Sanz Santillana, IMI/HARMONY
Lung Cancer Screening
Tõnu Esko, Estonian Genome Center
David Boyd, AstraZeneca
Chris Round, Merck
James N'Dow, Urology
Pierre Meulien, IMI
Stanimir Hasurdjiev on patient access
Mark Lawler, QUB
Tit Albreht, on screening
Etienne Richer on research in Canada

Other useful links

'Barriers' document
Special issue: Personalising Your Health: A Global Imperative
2025 Framework EAPM

Richard Sullivan, Kings College London

Virginia Acha, MSD, and below, Ruth March of AstraZeneca

Fabien Calvo, Institute Gustave Roussy and, below, Samuele Butera, Novartis

Desmond Schatz, University of Florida Diabetes Institute, and Nuria Malats, Spanish National Cancer Research Centre

Ulrich Jäger, Mediacl Universtiy of Vienna

Centre: Stéphane Hogan, DG Research & Innovation, European Commission and, below, Mary Baker, Past President European Brain Council

Third Annual Summer School for HCPs

WARSAW

The European Alliance for Personalised Medicine will run its third Summer School for young healthcare professionals in mid-2018, building on the success of the past years' events in Portugal and Romania.

Once again entitled 'TEACH' (Training and Education for Advanced Clinicians and HCPs), the school will be held in Warsaw, Poland, and will run from 19-22 June.

The Summer School will be centred around the concept of personalised medicine and the fact that it starts with the patient. It holds huge potential for improving the health of many citizens and ensuring better outcomes of health systems' efficiency and transparency.

Yet, its integration into clinical practice and daily care is proving difficult given the many barriers and challenges to timely access to targeted healthcare that still exist as of today.

If personalised medicine is to be in line with the EU and Member State principle of universal and equal access to high quality healthcare, then clearly it must be made available to many more patients than it is now.

Part of what is required is a long-term approach to education for those at the front-end of this exciting new way of treating patients.

This means that all HCPs in close contact with patients or their patients' families need to be up-to-date with the current aspects of personalised medicine and its latest breakthroughs in order to better understand their patients' concerns.

This third Summer School aims to support the endeavours of EAPM to set up a Continuous Educational Programme on personalised medicine.

EAPM and the faculty at the Summer School are convinced that improvement in up-to-date skills among HCPs is vital to giving the right treatment to the right patient at the right time.

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

TEACH
Training and Education for Advanced Clinicians and HCPs

Belfast Congress: the writing's on the wall!

Angelina Thomas (top left), Darragh McArt (r), middle Ellen De Waal, bottom left Jens Rauch, bottom right Patrick Mooney.
Photos by Simon Pugh Photography

We have, top left, Brasanna Kumar and Lakshmi Santhosh, top right is Dimitar Georgiev. In the centre we have Nadia Pellanda Jandl with Tom Lillie to the right. The bottom row features Vladimir Ljubicic and Daniel Schneider.

Pictured are, top left, Alice Ormrod, while top right is John Field. In the centre is Christine Chomienne. The bottom row features Katherine Benson and Laura Smyth, with Stephen Robbins alongside.

We special thanks to our partners:

Platinum partners:

Gold partners:

Silver partners:

Bronze partners:

About EAPM

The European Alliance for Personalised Medicine (EAPM), launched in March 2012, 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.

As the European discussion on personalised medicine gathers pace. EAPM is a response to the need for wider understanding of priorities and a more integrated approach among distinct lay and professional stakeholders.

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 EMA. EAPM is funded by its members.

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