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First Congress a great success at Belfast Waterfront

EAPM's first annual Congress came to an end after a long and busy few days and was a great success. We look forward to seeing many of you again at our conference in Brussels and at our next Congress in Milan.

Among the highlights of the final day in Belfast were a Presidential session on *Molecular Diagnostics – Enabling the Personalised Medicine Revolution*, co-chaired by David Barton of the National Centre for Medical Genetics in Crumlin, and Mario Pazzagli, from the University of Florence, Italy.

Pazzagli outlined 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", he said, "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."

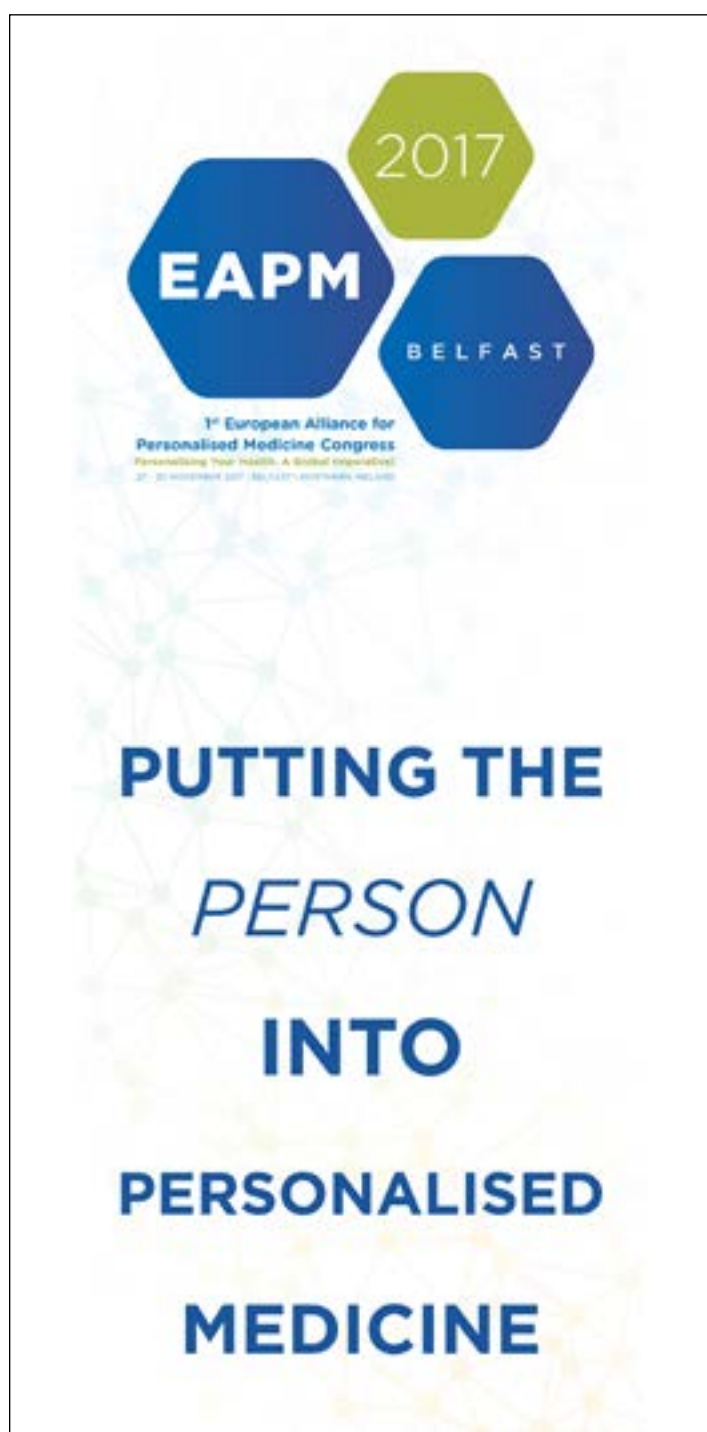
Pazzagli then went on to present some examples of workflows for molecular diagnostics in clinical oncology in which both aspects had been considered.

He told Congress: "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."

Meanwhile, yesterday afternoon, EAPM executive director Denis Horgan joined several others in officially wrapping-up the four-day Congress.

Horgan told attendees: "After we all go home from this Congress, EAPM will be pulling together the key messages that have emerged, through consensus, this week. The Alliance will do this with the intention of passing our important messages on to the European Commission, Parliament and Member State healthcare officials.

"It is clear that we need to engage at all political levels





Juergen Scheuenpflug, MSD, speaks to attendees in the session on the balance of patient safety and facilitating innovation. Photo by Simon Pugh Photography

and you can rest assured that, as ever, the Alliance will do this in its role as a platform for all stakeholders in the arena of personalised medicine."

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

He went on to say: "As has been pointed out many times this week, 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 the stakeholders cannot speak with one voice.

"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."

Other sessions included '*Regulating the future – Balance of patient safety and facilitating Innovation*' which reported to Congress that creating European unity, a journey that started 60 years ago, continues to be an ambitious and forward-looking endeavour.

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.

Earlier, during a session entitled '*The Challenges of Precision Oncology Drug Development and Implementation*', 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.

The session '*HTA, Payers & the European Medicines Agency – Crossing the Rubicon*' told Congress that one of the major

Sign of the times: more attendees in Belfast

We have, 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. *Photos by Simon Pugh Photography*





European Alliance for Personalised Medicine



illumina's Paul Jones. Photo by Simon Pugh Photography

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.

Special issue now available

Many of you will have seen that we have produced a special issue to coincide with the Belfast Congress. Those of you who didn't pick up a copy can download it [here](#).

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 both the public and healthcare professionals need to get up-to-speed.

These are just some of the issues facing us, but all is not lost if we act swiftly...

● *Healthcare: Europe's challenge*

Creating European unity, a journey that started 60 years ago, continues to be an ambitious and forward-looking endeavour. The European Union started as a dream of few and became the hope of many.

The EU's four fundamental freedoms – a distant dream and goal in 1957 – are now functioning and accepted as self-evident. Europeans have been living together in peace for longer than ever before. European citizens and companies enjoy unprecedented freedoms and prosper across the globe. It is inconceivable that a continent capable of so much should not be capable too of extending the benefits of innovative health policy to its citizens.

In just the same way that the world is hovering on the brink with climate change, with the stakes so high that getting it wrong this time round may spell disaster, Europe's hesitancy over healthcare reforms risks leading to irremediable meltdown of health systems – and of Europeans' health.

Getting it right the next time round may no longer be an option for Europe. For healthcare, as for other major challenges of our time, there may not be a "next time".

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,
Istituto 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."



Brian Aylward, of the Health Products Regulatory Authority, Dublin. Photo by Simon Pugh Photography

● A capacity for change?

Do we, as a society, have the capacity to tackle such big questions 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 and 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.

Framework: EAPM's vision from now until 2025

While covering many individual topics, the framework booklet, entitled '*From here to 2025: personalised medicine and healthcare for an immediate future*', sets out how 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 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



Washington's Lou Garrison addresses Congress yesterday. Photo by Simon Pugh Photography



Estonian Presidency
of the Council of the
European Union

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 the 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*

Download it [here](#)

Coming up in 2018

MEGA project

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 economy, and improving patient care across the EU.

Next-generation gene sequencing technologies provide physicians with the ability to make educated diagnoses based on a patient's genome which will lead to better health outcomes.

With rising healthcare costs an increasing challenge, genomics has the potential to reduce costs by ensuring that patients receive the right information and the right treatment at the right time.

Great leaps in genetic science, imaging techniques and apps that send information back to doctors show how fast science is moving. Meanwhile, the development of new drugs and treatments for cancers is having a significant impact and the emerging field of personalised medicine, which aims to give the right treatment to the right patient at the right time, is quickly gaining ground.

The latter relies heavily on genetic science and also heavily on medical Big Data, much of it genomic, which needs to be gathered, stored, shared and used efficiently - albeit under robust ethical and privacy rules.

The Alliance firmly believes that MEGA is a viable project. It is just as much a vehicle for advancing personalised medicine in Europe as it is for bringing together actors from different Member States to overcome the fragmented research environment.

MEGA could serve as a flagship for dealing with issues that have prevented European cooperation to date. In the end, it is all about the patients. And the MEGA project will certainly benefit them hugely down the line.

Sixth annual conference in Brussels

Plans for EAPM's sixth annual Presidency conference 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.



Above is Inaki Gutiérrez-Ibarluzea, bottom left is Nuria Malats and, right, is Tit Albrecht. Photos by Simon Pugh Photography



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.

Congress in Milan

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.

A key aim of the Congress is to allow crossfertilisation 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

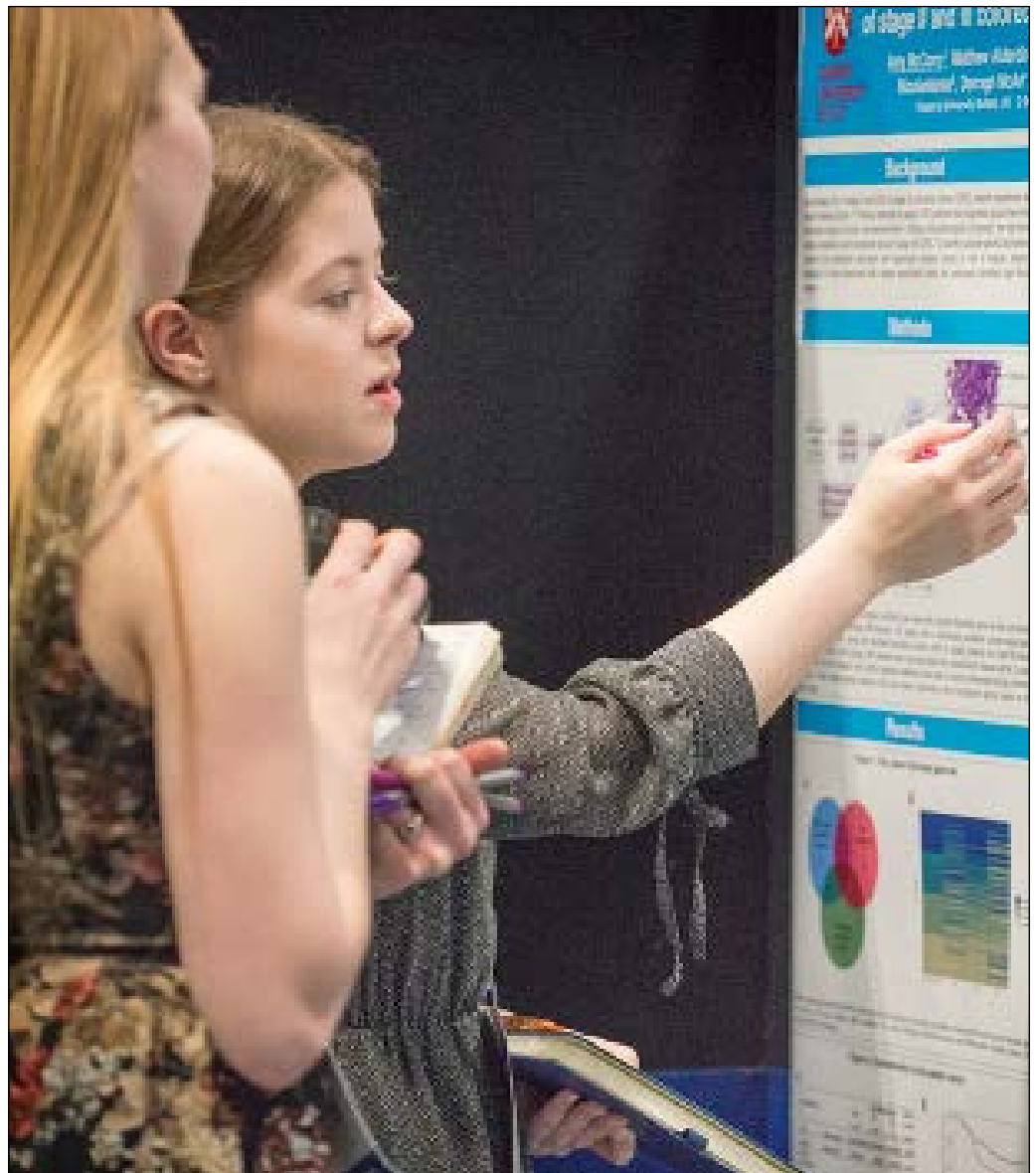
Videos from Belfast

EAPM recorded several video interviews in Belfast. Please follow these links:

- <http://bit.ly/BusoiMEP>
- <http://bit.ly/NolanHealthReg>
- <http://bit.ly/MerckCRound>
- <http://bit.ly/AstraZBoydAward>
- <http://bit.ly/SMARTMaltaAward>
- <http://bit.ly/HarmonyIMI>
- <http://bit.ly/LungCancerLancet>
- <http://bit.ly/ChomiennelNCA>

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.



Twitter hashtag for the Congress was:
[@eapm2017](https://twitter.com/eapm2017)



European Alliance for
Personalised Medicine



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



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Estonian Presidency
of the Council of the
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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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