



European Alliance for Personalised Medicine

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Countries and Commission sign up to MEGA

Welcome to our May newsletter.

April saw a major achievement for the Alliance and its stakeholders when, at the European Commission's Digital Day 2018 held in conjunction with the Bulgarian EU Presidency, 15 countries signed a [Joint Declaration](#) to collaborate on a groundbreaking one-million genomes project.

In front of high-level stakeholders in the fields of digital technology and telecommunication, representatives of Member States co-signed the Declaration indicating political support for linking existing and future genomic databanks.

This will work on a voluntary basis with the goal of making a cohort of one million sequenced genomes accessible in the EU by 2022.

The declaration was signed on 10 April by representatives of the European Commission and Croatia, Cyprus, the Czech Republic, Estonia, Finland, Greece, Italy, Lithuania, Luxembourg, Malta, Portugal, Slovenia, Spain, Sweden and the UK.

It was a truly significant moment that took a great deal of organisation, argumentation and persuasion.

EAPM originally floated the idea under the banner of MEGA - Million European Genomes Project - and with the leadership of DG CONNECT, the dream is about to become reality.

Meanwhile, as you will be aware, the Alliance has had legislative engagement with the European Parliament, European Commission and European Council proposing amendments in the areas of Data Protection, the Clinical Trials Regulation, In Vitro Diagnostics and also amendments supporting IMI on Horizon 2020.

For the General Data Protection Regulation (known as GDPR), EAPM made many suggestions and recommendations during the process.

Over the past few years, EAPM has produced many tangible outcomes, with many and varied stakeholders now considering us as the go-to organisation in the field, due to our ability, together, to deliver real change and progress.

How the day unfolded

Mariya Gabriel, Commissioner for Digital Economy & Society, addressed the event and was followed by a panel discussion.

In the pipeline for 2018

- **20 May: Rare diseases survey closes**
- **6 June and 11 July: HTA roundtables, European Parliament, Brussels**
- **19-22 June: Third TEACH Summer School for healthcare professionals, Warsaw**
- **26-28 November: Second Annual EAPM Congress, Milan**

Members of the panel included EAPM co-chair and former Commissioner for Health and Consumer Protection, David Byrne.

David was joined onstage by ministers and MEPs from Italy, (Beatrice Lorenzin - Health) Malta (Evarist Bartolo - Education and Employment), Portugal (Adalberto Campos Fernandes - Health), Estonia (Siim Sikkut - Economic Affairs), Bulgaria (Andrey Kovatchev - Member of the European Parliament), Spain (Juan Maria Vasquez Rojas - Economy, Industry and Competitiveness), and the UK (Lord James O'Shaughnessy - Health and Social Care).

Evarist Bartolo said that a big challenge is that most people working in healthcare have been trained for the pre-digital world, adding that it's not the technological factor or the finance factor, but the human factor.

Italy's Beatrice Lorenzin said that, since 2012, her country has been investing a lot in personalised medicine, as well as in the genomics sector. It is important to have a lot of data for research in this area, she told the audience.

Adalberto Campos Fernandes, from Portugal, emphasised the need to shape sustainable healthcare and that personalised medicine, while a challenge, is also an opportunity to provide better healthcare.

For the UK, Lord O'Shaughnessy said there can sometimes be scepticism about whether data is being used properly, stored securely and used legally. But, he added, when it is clearly benefiting an individual through their care pathway, it makes it much easier "to bring people with you".

"Cooperation is important," he added, explaining that sharing



Top: Square venue, which hosted Digital Day 2018

Above: From left, Eelko den Breejen (Roche), David Byrne (EAPM), Mariya Gabriel (European Commission), Paul Jones (Illumina), Denis Horgan (EAPM), and Mario Romao (INTEL)



Pictured top left is Mariya Gabriel (European Commission) while the two other photos show scenes from panel discussions and the signing of the Declaration



Pictured is **Andrey Kovatchev (Member of the European Parliament)**

the data across the EU would speed up the benefits.

Bulgarian MEP Andrey Kovatchev told the Digital Day audience that collecting data for personalised medicine and genomic sequences should indeed be a combined effort, while Spain's Juan Maria Vasquez Rojas said that cooperation was compulsory to improving health standards "today and in the near future".

Estonia's Siim Sikkut said his country was investing and trying to "chip in quite a bit to the joint effort" and are "big fans of this Declaration" while suggesting a bigger goal than one million genomes down the line.

David Byrne said it is necessary to federate the stakeholders and that collaboration is essential. He went on to remind listeners that it wasn't just the sequencing, but that it was necessary to do the research on the outcome of the MEGA project, converting it into medical information to provide good medical outcomes for the patients of the European Union.

"Not only can we do it, we must do it," he added. On governance, Byrne said that there has to be a public institution heading this that is accountable to the public.

After the Digital day event, the European Commission issued a statement, part of which read as follows:

"Ministers and representatives of Member States recalled their commitment to complete the Digital Single Market, and agreed to work together more in a series of key areas for Europe's future: artificial intelligence, blockchain, ehealth and innovation.

"Today's commitments by Member States give a strong signal: we all understand that Europe's future is digital and that the only way to fully reap the benefits of new technologies is by working together, joining forces and resources.

"We are creating a strong Digital Single Market – let's build on this to make sure that Europe has a bright digital future."

The European Commission understands that data-driven innovation is a key enabler of market growth and the

development of new technologies. It allows citizens to easily access and manage their health data, and allows public authorities to use data better in research, prevention and health system reforms.

Commissioner for Health and Food Safety Vytenis Andriukaitis said: "Our proposals make use of the full potential of digital technologies to improve healthcare and medical research. This will lead to easier access to health data, which will lead to better disease prevention and patient-centred care, rapid responses to pandemic threats, and improved treatments."

Commission Vice-President for the Digital Single Market Andrus Ansip said: "The Digital Single Market is rapidly taking shape... Technologies can help us to improve healthcare and education, transport networks and make energy savings: this is what the smart use of data is all about.

Meanwhile, Commissioner for Digital Economy and Society Mariya Gabriel added: "We are pursuing an ambitious plan, the Digital Single Market Strategy, to make sure that we are in the best possible position to help our businesses, provide top-class research, and protect EU citizens."

The Commission says its proposals will build on the GDPR, which will enter into force as of 25 May. Read more [here](#)

Sofia so good

Another key event last month was a major lung-cancer screening conference in Sofia (22-23 April) under the Bulgarian Presidency (which lasts until 30 June).

The conference was run by national affiliate the Bulgarian Alliance for Precision and Personalised Medicine in association with EAPM.

The event's title was '*Lung cancer and early diagnosis - The evidence exists for screening*'.

The Bulgarian Alliance has taken a lead in putting access and



Pictured to **Giulia Veronesi (Humanitas)**

earlier diagnosis as a top priority in its own region as well as in the Balkans. Sofia sees it as vital to focus on screening and prevention, especially in respect of such a killer disease.

Jasmina Koeva, of the Bulgarian Alliance (BAPPM), led the conference and said: "One of the aims is to put forward a recommendation to be adopted by the EU Council to facilitate the drawing-up of lung-cancer screening guidelines by an Expert Group.

"This will take into account the pros and cons of screening programmes in other disease areas, including breast, colorectal and cervical cancers."

She added: "Europe is looking at risk prediction models to identify patients for screening, plus determination of how many annual screening rounds are required.

"There have been indications that, while we wait, there is a good case for immediate implementation of carefully designed and well-targeted demonstration programmes."

Lung-cancer screening was the top topic of last year's EAPM Presidency conference, and this follow-up event will carry the baton further.

Figures show that lung cancer causes almost 1.4 million deaths each year worldwide, that's almost one-fifth of all cancer deaths.

Within the EU, meanwhile, lung cancer is also the biggest killer of all cancers, responsible for almost 270,000 annual deaths (some 21%).

Alongside Jasmina Koeva, also speaking at the Sofia event were Andrey Kovatchev and Alojz Peterle both Members of the European Parliament, Serban Ghiorghiu of AstraZeneca, the European Commission's Ciaran Nichol, Oleg Petkov, Deputy Minister for the Bulgarian Presidency of the Council of the EU, and Denis Horgan, EAPM's executive director.

In this fast-moving world of personalised (or precision) medicine, with incredible breakthroughs in genetic mapping and super-efficient diagnostic tools, broad-based screening programmes in certain disease areas, recommendations on the same, and information readily available on the internet, how much knowledge do patients want about their own conditions?

And how much do some healthcare professionals (HCPs) actually believe patients can handle? And what about the patient's close family - do they need to know all the facts, or do they need to be protected?

One could argue that it has long been the norm for governments, presidential candidates or, indeed, campaigners on either side of a complex referendum to 'dumb down' issues to make it easier for 'the masses' to understand them (or, to be more cynical, to misunderstand them in certain cases).

That's just the way it is, but is this permissible in the arena of health? Do HCPs of whatever nature have the right to be patronising in certain cases when believing that a patient may not be able to handle all the facts, say, after a prostate PSA test or a breast-cancer screening? Or even a full gene sequencing exercise that could show up genetically transferred diseases?

It's a moral minefield, but for their part organisations such as ourselves believe that the patient should be empowered, play a key role in the decision making about his or her condition and, therefore, have all the necessary knowledge of their condition, potential treatments, clinical trial options and to be briefed on the best drugs available to them while taking into account any possible or probable side-effects, their work and lifestyle, and their own perceptions of what constitutes 'quality of life'.

Certainly, many people would not want to run full DNA sequencing. In certain cases, a healthy patient would be able to learn about the likelihood that they would eventually develop one or more diseases, perhaps through heredity (which obviously affects close family members, too).

Would they really want to spend the rest of their lives worrying about this? And would it lead to over-treatment or even totally unnecessary treatment, at a high cost to them emotionally and at a high cost to society in general?

Conversely, though, a woman whose grandmother, mother or sister has developed a particular form of breast cancer, or a man whose father and uncle both suffered from prostate cancer, may very well wish to gain all the knowledge available about the likelihood of she or he developing the diseases too.

In these circumstances the phrase 'prevention is better than cure' certainly rings true. A report from the event will be published later this month.



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Bulgarian Presidency of the Council
of the European Union

Other April meetings

EAPM was represented by speakers at the 7th CNAG Symposium on *Genome Research: Personalised Medicine* (12 April) and at the EFA Annual General and Patient Leaders Meetings, hosted by APA and RESPIRA (16 April).

HTA proposal

Back in March, the Alliance held a roundtable discussion in respect of the regulation of the European Parliament and Council on health technology assessment and the amending directive 2011/24/EU.

The event took place against the backdrop of the recent European Commission legal proposal on plans for future cooperation among EU countries on determining the added value of new therapies.

It heads in the direction of mandatory use of joint clinical assessments reports, after a three-year transition period. In theory, it could go a long way to allowing medical bodies to catch up with a scientific arena that is moving forward quickly.

An early problem, though, is that four Member States feel that the plans veer too far into national competencies. They are Germany, France, Poland and the Czech Republic.

What the Commission is looking for in this case includes "patient-relevant health outcomes," and a "degree of certainty" of those effects.

Major advances in healthcare are just around the corner, with a wealth of new possibilities promised for European patients and society through the increased adoption of personalised approaches to medicine.

The bottom-line is that the EU is beginning to realise that systems need to catch up with science.

With the help of our STEPs group of MEPs, we are organising two roundtables in the Parliament to cover the issues arising from the proposal. The dates are 6 June (14.30-17.30) and 11 July (18.00-21.00).

A third meeting will be organised during the Austrian Presidency in September or October.

EAPM's meetings are timed to give representative stakeholder input in to the Parliament as follows:

- *Draft report sent to translation* - 7 May
- *Consideration of the draft report* - 7 June
- *Deadline for amendments* - 13 June at 11:00
- *Consideration of amendments* - 9/10 July
- *Vote in ENVI (+mandate)* - 10 or 13 September or mandate in October
- *Plenary* - October

Rare diseases survey

Our latest survey is now open. This survey on rare diseases aims to measure progress on access and orphan drugs. To participate, click [here](#)

As part of its ongoing work in the fast-developing sector, the EAPM survey will cover recent developments and the current status of R&D into rare diseases, the current system of incentives for rare disease companies and biotech, as well as the role of Health Technology Assessment in the personalised medicine era.

Aimed at its EU and national multi-stakeholder base, which includes patients and their advocacy groups, healthcare professionals, researchers, politicians, industry representatives, academics and more, the survey will run until 20 May.

Topics specifically covered in the questionnaire include stakeholder satisfaction or otherwise regarding the pace of research into rare diseases over the past 15-or-so years.

The year 2000 saw the entry into force of the Orphan Regulation, adopted by the EU to encourage the development and authorisation of medicinal products for rare diseases.

Third Summer School set for Warsaw

EAPM's third annual Summer Summer School will be held in partnership with the Polish Alliance for Personalised Medicine and will take place in Warsaw from 19-22 June. The title of this year's edition is *New Horizons in Personalised Medicine*.

There is a great need for constant education in clinical implementation of the personalised medicine, not least based on pharmacogenomics, pharmacogenetics, pharmacoproteomics, and metabolomics.



Pictured is **Stanimir Hasurdjiev (Patient Access Partnership)**

This third international Summer School will give participants a unique opportunity to have discussions with, and learn from, leading experts (from Poland and beyond) in medical oncology, gastroenterology, cardiology, radiation oncology and radiology, as well as in clinical and translational research, and more.

November Congress heading for Milan

The second annual EAPM-run Congress will take place in Milan from 26-28 November, and we hope to see you all there. The report from last year's Congress in Belfast is available [here](#).

More than 1000 Life Sciences thought leaders are expected to convene at the Congress and, as it did last year in Belfast, the event will bring together key audiences who contribute to the vast programme content, themed tracks, and vital knowledge exchange. Learn more, [here](#)

In the news

As ever, the Alliance has been busy engaging with the media. Below you can find links to recent articles.

[Tipping the health-care balance through patient knowledge](#)

[Digital Day to set ball rolling on one-million genomes project](#)

[Big push for lung-cancer screening from Sofia](#)

[Survey on rare diseases to measure progress on access and orphan drugs](#)

['Let the EU Stars Shine' for lung cancer screening](#)

[Post-Digital Day initiative on health data backed by Commission](#)



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About EAPM

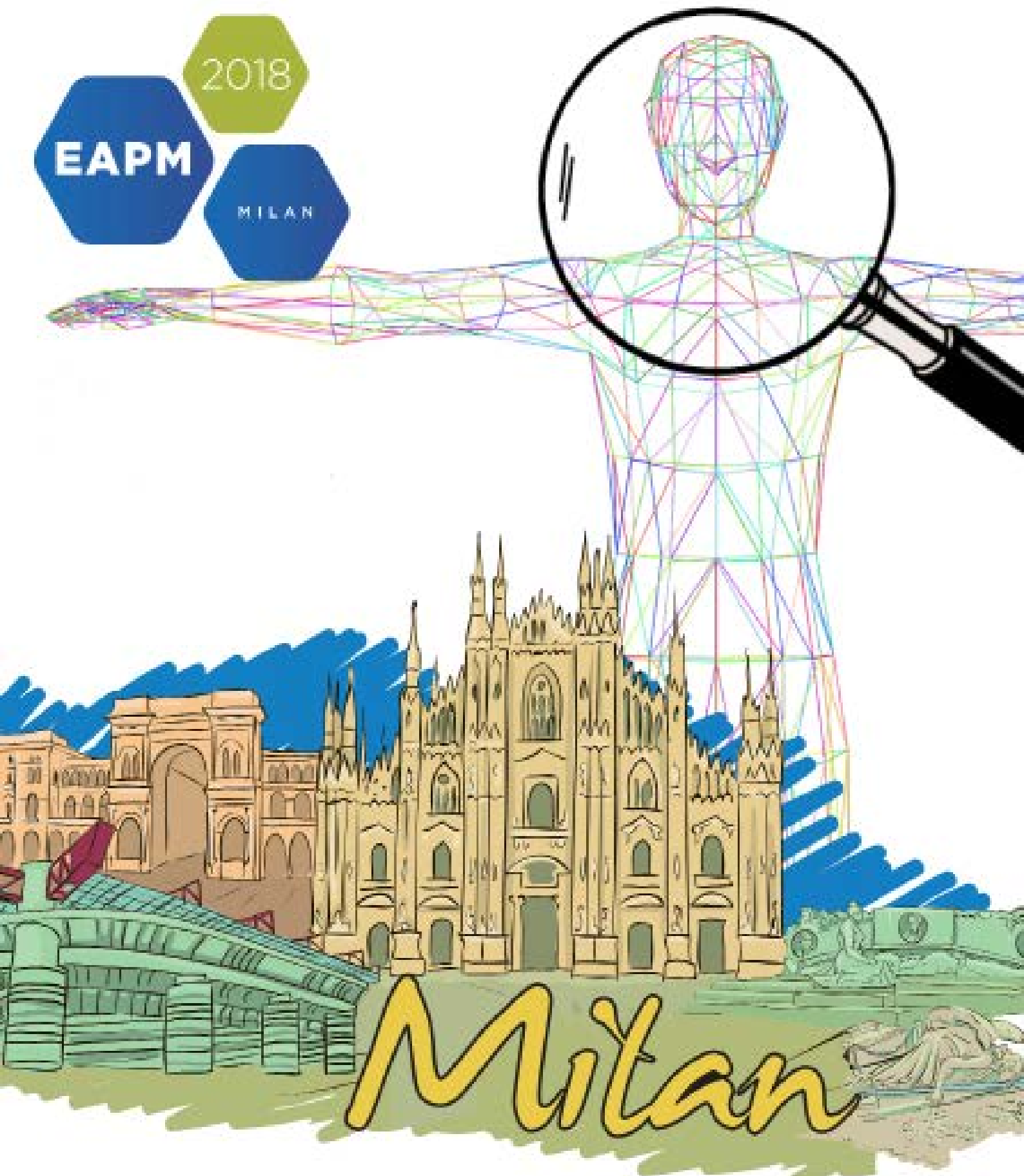
The European Alliance for Personalised Medicine (EAPM) , launched in March 2012, brings together European healthcare experts and patient advocates involved with major chronic diseases. The aim is to improve patient care by accelerating the development, delivery and uptake of personalised medicine and 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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