



# European Alliance for Personalised Medicine

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[www.euapm.eu](http://www.euapm.eu)

## Conference is perfect Easter present!

The 2018 EAPM conference is now behind us, so take a look at the photo spread in this April newsletter, for a quick recap. The report will be available online in due course, so we'll keep you posted.

Meanwhile, we hope you all enjoy the Easter break.

Suffice it to say, the sixth annual Presidency conference - like the first five editions - was a great success, with the usual broad spread of high-level stakeholders and EAPM members joining us at the historic Biblioth  que Solvay in Brussels, as well as the European Commissioner for Health and Food Safety, Vytenis Andriuskaitis.

Some 150 delegates were in attendance, including several Members of the European Parliament, as well as representatives from relevant ministries and Commission directorates-general.

Also present were representatives of the European Medicines Agency.

Each session developed concrete policy asks that were outcome of the sessions that were linked to bring life to the EU Council Conclusions from Luxembourg on patient access to personalised medicine and Estonia's conclusions on health on the digital society.

### **Digital Day 2018**

As ever, EAPM will continue its engagement with the European Parliament in order to understand their position and concerns when it comes to ensuring the best quality of treatment for the EU's patients, while conveying the priorities of our members and other stakeholders to them.

The over-riding topic of this year's conference was '*Personalised Medicine and the Big Data Challenge*', and included a focus on EAPM's MEGA project, which stands for 'Million European Genomes Alliance'.

This aims to gather one million genomes from across Europe for research purposes through a coalition of willing Member States and will be a feature of [Digital Day 2018](#), coming up on 10 April.

This second Digital Day aims to reach joint commitments related to the digital future of Europe in order to encourage investment in European digital technologies and infrastructures.

A digitally strong EU will contribute to a competitive and

### **In the pipeline for 2018**

- **10 April: Digital Day 2018**
- **22-23 April: 'Lung Cancer Screening - Moving forward towards guidelines', Sofia**
- **19-22 June: Third TEACH Summer School for healthcare professionals, Warsaw**
- **26-28 November: Second Annual EAPM Congress, Milan**

socially secure society, better public services, and better security.

Digital Day 2018 also aims to follow up on commitments made at last year's Digital Day in Rome.

That event was part of the official celebrations marking the 60th anniversary of the Treaties of Rome, and looked at topics that will have an impact on the near and long-term future of EU citizens.

Attendees in April will witness the signing of a Declaration by a 'coalition of the willing Member States' to take the first steps to realising the goal of collecting, storing and sharing one million European genomes for health research.

It will be a very exciting moment although, of course, the signing of the document is merely the first step in a long journey.

However, it certainly appears as though the political will is there, and we at the Alliance are now developing an action plan to make this a reality going forward. A unique opportunity to lead the next wave of breakthrough innovation, especially in areas where digital technology meets the physical world.

### ***Sofia conference on lung-cancer screening***

The Bulgarian capital of Sofia will host a conference on lung-cancer screening, also in April, during the country's first-ever term at the helm of the rotating EU Presidency (until 30 June).



**Top: Former European Commissioner and EAPM co-chair David Byrne congratulates current EU Commissioner for health and food safety, Vytenis Andriukaitis, on his speech. The picture, on the left, shows the venue - Bibliothèque Solvay, in Brussels - and above right is Kaisa Immonen, of the European Patients Forum.**

*Pictures by Simon Pugh Photography*





*Pictured top left is Iñaki Gutierrez Ibarluzea, Vice President Health Technology Assessment international, based in the Basque Region of Spain, top right is EAPM board member Mary Baker and above is Gordon McVie, the Alliance's co-chair.*

*Pictures by Simon Pugh Photography*



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Bulgarian Presidency of the Council  
of the European Union

In association with EAPM, the conference will be run by national affiliate the Bulgarian Alliance for Precision and Personalised Medicine.

The Bulgarian Alliance has taken a lead in putting access and 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.

One of the aims of the conference 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.

It is anticipated that the conference will conclude with the signing of a declaration for this purpose and the next step is to persuade the European Commission to take action in this area.

Many readers will recall that as a result of last year's EAPM Presidency conference, the Alliance engaged health experts with two articles that we believe provide the scientific justification for widespread screening for lung cancers.

The first, '*European position statement on lung cancer screening*' is available [here](#), while the second, entitled '*EU Policy on Lung Cancer CT Screening 2017*', can be found [here](#).

Meanwhile, more information on the Sofia event is available by clicking [here](#).

#### ***Survey on rare diseases***

As part of its ongoing work in the fast-developing sector, the EAPM will launch a survey regarding recent developments and 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 (HTA) 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 be launched on **9 April**.

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

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

An orphan drug is a pharmaceutical agent that has been developed specifically to treat a rare medical condition, otherwise known as an orphan disease.

Since the Regulation, the Commission has said, there has



been “impressive progress, in particular as regards generating significant activity by the pharmaceutical industry in this field”.

But do EAPM's stakeholders agree with that assessment? Have your say in the survey, which you will receive in the near future.

The survey coincides with the announcement of recent plans by the European Commission to introduce mandatory use of joint clinical assessments reports in HTA, after a three-year transition period - a move welcomed by EAPM.

Under the Commission's proposal, HTA bodies in Member States would be required to use the clinical assessment and “no repetition” of it in their overall processes. A key aim of the new Commission proposal therefore is to improve cooperation and reduce duplicated work across the bloc.

### ***HTA roundtables in the pipeline***

As mentioned above, the European Commission issued a new proposal on plans for future cooperation among EU Member States when it comes to determining the added value of new therapies.

In early March, the EAPM held a roundtable discussion in respect of this proposed movement, and among organisations represented at the meeting were Roche, MedTech, Sanofi, ESMO, Siemens, JDRF, the European Patients Forum, Alexion, ECPC and the European Society of Radiology.

The European Commission legal proposal plans 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 necessary medical bodies to catch up with a scientific arena that is moving forward quickly.

By the end of the transition, “all medicinal products falling within the scope and granted marketing authorisation in a given year will be assessed”. This also covers selected medical devices.

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

EAPM is lining up several meetings to tackle topics arising from the Commission's move. The dates of the meetings to be held in the Brussels European Parliament (above) are yet to be finalised, although two will be held before the summer break, with the third (a public meeting) to be held later in the year.

Each upcoming EAPM meeting will feature two themed issues, with the first meeting discussing Joint Clinical Assessments alongside Joint Scientific Consultations, as well as stakeholder involvement in the context of the HTA Coordination Group.

Expected key outcomes of the roundtable series will be joint understanding, consensus building and the proposal of amendments. This will take place in collaboration with European Parliament rapporteurs, the shadow rapporteurs and





representatives from Member State.

As ever with EAPM events, these stakeholders will be complemented by experts representing patient, clinician and research perspectives, among others. Watch this space...

### ***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.

Personalised medicine dramatically changes the way medicine is practiced. It relies on genetic, molecular and deep clinical data and enables medicine to be practiced in a more efficient and effective manner.

In the near future such precision in treatment will reshape drug and biologic development, advance our understanding of the pathogenesis of disease, eliminate waste from our healthcare system, and improve the overall quality and efficiency of care.

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

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.

Once again, the school will come under the banner of 'TEACH', which stands for Training and Education for

Advanced Clinicians and HCPs, and the goal is to bring young, front-line professionals up-to-speed with fast-moving developments in the field.

If personalised medicine is to be in line with the EU principle of universal and equal access to high-quality healthcare, then clearly it must be made available to many more citizens than is currently the case.

Ongoing HCP education can help to make this happen.

### ***November Congress heading for Milan***

The second annual EAPM-run Congress will take place in Milan from 26-28 November at the prestigious MiCo venue, and we hope to see you all there. The report from last year's Congress in Belfast is available online, [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.

Don't miss the opportunity to join large numbers of industry professionals, government regulators, patients, researchers, academia, healthcare professionals, journalists and exhibitors to drive insights to action.

More than ever this year, a focus will be on the upcoming European Parliament elections and the installation of a new College of Commissioners, tasked with devising and implementing regulatory frameworks in all areas, including certain aspects of health.

More than 700 MEPS will be elected next summer and the



Commission will also have a new president as Jean-Claude Juncker steps down.

One of the goals of Congress is to engage politicians and lawmakers in the fast-growing field of personalised medicine, and deliver political asks through our consensus-based process.

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.

[Warsaw forum tackles personalised medicine on the ground in Poland](#)

[Facing up to the economics of genomics in the personalised medicine era](#)

[Primary health care needs to abandon the status quo, Commission report states](#)

[Europe too slow at bringing innovation into healthcare systems](#)

[Digital single market angel Gabriel deserves more support](#)

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#### **About EAPM**

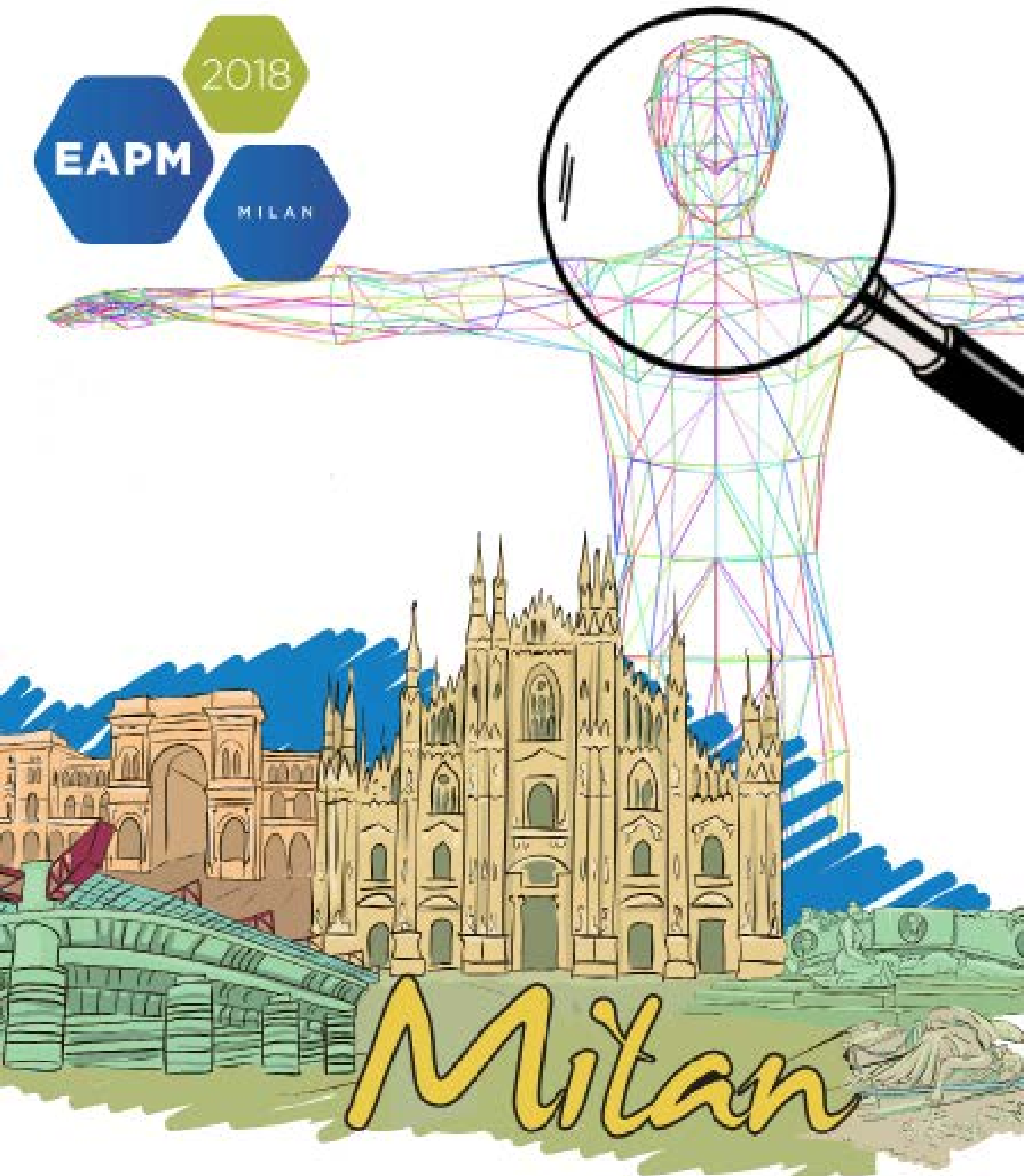
**The European Alliance for Personalised Medicine (EAPM) , launched in March 2012, brings together European healthcare experts and patient advocates involved with major chronic diseases. The aim is to improve patient care by accelerating the development, delivery and uptake of personalised medicine and 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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**EAPM**  
2018  
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**2nd European Alliance for  
Personalised Medicine Congress**

**26 - 28 NOVEMBER 2018**

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