



European Alliance for Personalised Medicine

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Germany at the helm for 2020 part two

Hello and welcome to EAPM's newsletter for July. Before we get into the newsier items, just a reminder that today (Monday 29 June) is your last opportunity to register for our virtual conference taking place on 30 June.

You've had plenty of info down the weeks to whet your appetite, so do join us if it is at all possible..

Lung-cancer screening latest

Since 2016, the Alliance has been working tirelessly to push for comprehensive lung-cancer screening programmes at the EU level complete with best practice exchange and, importantly, recommendations and agreed and properly implemented guideline.

EAPM's executive director **Denis Horgan** and distinguished others have come under the leadership of Milan's finest, **Giulia Veronesi**, to publish, in journal MDPI, an article on *Recommendations for Implementing Lung Cancer Screening with Low-Dose Computed Tomography in Europe*.

The link to the full article is [HERE](#).

The article explains that lung cancer screening (LCS) with low-dose computed tomography (LDCT) has been demonstrated in the National Lung Screening Trial (NLST) to reduce mortality from the disease.

Meanwhile, European mortality data has recently become available from the long-awaited Nelson randomised controlled trial, which confirmed lung cancer mortality reductions of 26% in men and 39–61% in women.

Recent studies in Europe and the USA also showed positive results in screening workers exposed to asbestos.

However, the article explains, the economic impact of LDCT-LCS and guidelines for its effective and safe implementation still need to be formulated.

It goes on to outline recommendations agreed by consensus.

Global conference 14 July

Coming up, on Tuesday 14 July, is another EAPM virtual gathering - our Global conference - entitled *Forward Together - Where we are now and the necessary next steps for a resilient healthcare System - effective ways of investing in healthcare in a COVID-19 and Post COVID-19 World*.

In the EAPM pipeline:

- **14 July, 2020 - EAPM Global Conference - Forward Together - Where we are now and the necessary next steps for a resilient healthcare System' - effective ways of investing in healthcare in a COVID 19 and Post COVID 19 World**
- **18-19 September: ESMO Roundtable - Madrid, Spain**
- **13-14 October: Virtual conference: "Building a decentralised, data-rich testing space to speed better testing and care in a Covid and post-Covid world"- Brussels, Belgium**
- **November: EAPM Global Conference - Brussels, Belgium**

Obviously, like everyone in our sector, EAPM is and has been as busy as ever during this dreadful crisis that we all find ourselves in, and the work to embed personalised medicine into healthcare systems and generally improve the health of all citizens goes on unabated.

We'd like you to join us at this high-level 'virtual' global conference, featuring two important seminars - one on Asia, the Middle East and the European Union, and the second focusing on the European Union, Latin America and North America.

The EAPM Global Conference will run from 08.00-19.00 on that day split between two time-zones (08.00-12.30, then 16.00-19.00), with discussions centred around the concept of personalised healthcare in the sense that it refers to innovative medical interventions tailored to the specific needs of individual patients, thus providing better treatment and preventing undesirable adverse reactions while fostering a more efficient and cost-effective healthcare system.

By taking stock of where we are globally in different regions in terms of access to personalised healthcare in these COVID-19 times, acknowledging challenges need to be overcome.

Meanwhile, by highlighting opportunities to accelerate progress in a post COVID-19 setting, the scene for further action can



be set. In this regard incentives on national, regional level and global-level as well as cooperation between countries are vital to make early access to personalised healthcare a reality for patients throughout every region globally.

There will be many Q&A sections, so everyone will have the opportunity to contribute.

Objectives:

The over-riding goal in all areas today is to identify and fill the implementation gap that exists when aiming to introduce innovation into Global healthcare systems at a faster and quicker pace.

This involves developing policy frameworks in relevant sectors, building on global frameworks such as EU Council Conclusions on personalised medicine as well as the Precision Medicine Initiative in the US, and developing a workable framework for cooperation going forward, while building bridges between stakeholders, many and varied across different regions globally.
Expected outcomes:

It is necessary to formulate a patient-centred strategy involving EU 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.

An agenda is also available - [HERE](#). We do hope you can join us for this important online meeting.

Newsbeat

According to the World Health Organisation, the EU and broader Europe has seen an increase in weekly cases of COVID-19 for the first time in months as restrictions imposed to curb the spread of the virus are eased.

Eleven unnamed countries have seen accelerated transmission lead to "very significant" resurgences, in the words of WHO Regional Director Dr **Hans Henri Kluge** (above).

He reminded everyone that his warnings about the risk of resurgence had become reality, and further warned that, if left unchecked, our health systems would be "pushed to the brink".

More than 2.6 million cases of Covid-19 and 195,000 deaths have been reported in the WHO's European region. This covers 54 countries and seven territories across Europe, the Middle East and Central Asia.

In the region of 20,000 new cases and more than 700 new deaths are being recorded daily.

Dr Kluge said: "For weeks, I have spoken about the risk of resurgence as countries adjust measures. In several countries across Europe, this risk has now become a reality - 30 countries have seen increases in new cumulative cases over the past two weeks.

"In 11 of these countries, accelerated transmission has led to very significant resurgence that if left unchecked will push health systems to the brink once again."

He did, however, say that the WHO anticipated that the situation would calm down further in the majority of countries over the summer.



"But we have indeed to prepare for the fall, when COVID-19 may meet seasonal influenza, pneumonia, other diseases as well, because ultimately the virus is still actively circulating in our communities and there is no effective treatment, no effective vaccine, yet."

More second wave fears

As you can see, much has been said about second waves and local breakouts, not least recently after the UK - following in the footsteps of the likes of Germany - saw Prime Minister **Boris Johnson** announce the rowing back of many restrictions and the re-opening of a wide range of business permissible from 4 July.

Realistically, there will be more local lockdowns and if scientists are to be believed there will certainly be some kind of a second wave. So some governments and, of course, many members of the general public are understandably a little nervous.

Europe's Health Commissioner **Stella Kyriakides** (pictured) in late June said that the Commission will publish a communication on the second wave on 15 July.

Worryingly, some Member States that didn't get hit the worst by the coronavirus initially, such as Romania and Bulgaria, are now reporting localised outbreaks.

At the same time, Greece and Denmark are warning about possible second waves, while Portugal's Prime Minister **António Costa** has imposed some stricter rules.

But as mentioned, Germany's facing its own new challenges, with numerous localised outbreaks. EAPM's supporter and German MEP **Peter Liese** has said he was "shocked" when his constituency was hit.

Liese thinks some indoor venues should be closed. For example, cinemas and restos. Also, he feels that citizens should be unable to use places such as nonessential shops for longer than 15 minutes,. Masks should be an absolute requirement, he believes.

"If we're not careful, we will have a general increase," he said.

While we have the spotlight on Liese, it is rumoured that while his party the EPP will get the chair of the European Parliament's Cancer Committee, he doesn't want the job personally.

The Renew Europe party will get the lead rapporteur role on the Cancer Plan - probably in the person of MEP **Véronique Trillet-Lenoir**.

Presidency can't side-step pandemic

Germany takes over the EU's rotating presidency from Croatia on 1 July (for six months until 31 December) and has firm goals to boost health digitalisation, as well as to address medicines shortages, finally sort out the health technology assessment proposal.

Trouble is, there's the small matter of COVID-19...

"In the EU, crises have always been an opportunity to question what is given and to prepare yourself even better for the future," the German Presidency has written, according to *Politico*.

"Our common task goes far beyond dealing directly with the current situation."

It plans to examine and build upon several existing EU measures, such as whether the joint procurement agreement could be quicker in addressing "supply bottlenecks" and whether the Civil Protection Mechanism can be improved by creating a "knowledge network for civil protection" to strengthen



cooperation across borders.

Meanwhile, it will also be looking at bolstering the European Centre for Disease Prevention and Control by building a database for “comparable data” around the EU.

Germany has also said it wants a “coordinated procedure” for ensuring equal access to tests, treatments and vaccines against coronavirus; strengthening the WHO; and making sure the EU is “an anchor of stability” in the world.

On another note, the country’s medical device industry is already powerful, and looks likely to ramp up its influence during Berlin’s six-month European Council presidency.

Germany’s **BVMed** lobby group has made its priorities known to German Health Minister Jens Spahn as well as Health Commissioner Kyriakides.

Topics at the top of the list are bringing medicines production back to Europe (with a note on concerns about environmental and bureaucratic regulations), tracking stockpiles, and “alternative evaluation procedures” to the Medical Device Regulation.

Conference on the Future of Europe

Staying with Germany... As we look towards the Conference on the Future of Europe, the country’s chancellor **Angela Merkel** says it shouldn’t merely focus on a few issues, adding “we could achieve concrete and tangible results in the foreseeable future”.

Merkel has some key things on her mind and, for the record, these include the further development of the Schengen system,

the modernisation of competition law to adapt it to the challenge of digitalisation and globalisation, the development of a Europe-wide pandemic preparedness, and the creation of a European Security Council in foreign policy matters. Someone is going to be very busy...

Commission health plans

The Commission is gradually putting together and revealing its health plans. And EAPM supporter Romanian MEP **Cristian-Silviu Buşoi** (above) is keeping an eye on it more than most as rapporteur for the health programme budget in the Parliament.

The MEP recently ran a Zoom seminar on the Commission’s €9.4 billion measure, of which he’s currently a supporter.

He noted that there are plenty of major health crises beyond coronavirus, including antimicrobial resistance and non-communicable diseases, adding that any cash should be used to make EU health systems more “resilient”.

Buşoi pointed out that most of the €9.4 billion health budget is front-loaded, meaning proposals need to be very concrete and clear.

For her part, MEP **Sara Cerdas** has said it’s “unfortunate” that it took the the emergence of COVID-19 for the Commission to boost the health budget.

Meanwhile, German Health Minister **Jens Spahn** has already called for a “health NATO”, while six EU Member States have expressed concern that we’re not ready for any future pandemic.



As it turns out, nearly all EU health ministers/national diplomats welcome the new standalone health programme **EU4Health**, with its drastically increased budget from the €413 million in the Commission's 2018 proposal.

For example, France's Secretary for Child Protection **Adrien Taquet** said: "This ambitious programme...sends a strong signal to our European citizens and on our intention to make health a priority."

Member States have also given the Commission the go-ahead to buy vaccines on their behalf, spending more than €2 billion on advance purchase agreements of coronavirus vaccines while they're being tested.

More EU influence on health?

Of course, the sub-text currently running as the pandemic itself runs on is the idea of giving more influence in health for the EU.

The European People's Party has now adopted a proposal going calling for "EU Health Sovereignty", which says it wants "an EU that is capable of empowering Member States to "prevent and manage future health crises in a more coordinated manner, while becoming less dependent on others."

Key aspects are avoiding future shortages, improving access to and availability of health data, and strengthening the EU's role in global health.

And the Commission's VP for Promoting the European Way of Life, **Margaritis Schinas**, likes Spahn's health NATO idea, but "we should proceed by stages", he said.

Schinas told *Politico*: "We will be tested whether this drive of the EU sovereignty on health will emerge when the vaccine will come or how the vaccine will come."

Then "it will be tested again in our new pharmaceutical strategy to make sure that pharmaceutical industry can produce what we need" and then again when the EU will have

to "revisit our industrial and production model to see why at these critical moments, Europe did not have masks or ventilators or paracetamol".

Over and above, the idea of giving the EU more power in health still has to overcome predictable objections caused by the closely guarded Member State competence.

The Commission says its proposals are staying within the treaties, but EU states are on the look-out, with national capitals already saying they want a bigger role in implementing the EU4Health programme.

Roland Driec, who is director of international affairs at the Dutch health ministry, said: "It's important to also keep Member States in the driver's seat...The proposed role of Member States in the execution of the programme seems too limited."

He was essentially backed by Ireland and Denmark, with the Czech Republic warning that the Commission's proposal went too far by overstepping its health competence.

Czech Deputy Minister of Health **Radek Policar** said: "We're concerned that some activities of the program might not respect exclusive competencies.

"There's no doubt that the activities improving health systems' resilience and sustainability must be supported," but he added that healthcare systems are a Member State competence.

EU Health Commissioner Stella Kyriakides has insisted that countries will get their say, telling them and us: "Member States will be involved at many different levels and programme objectives."

Kyriakides however argued that there's been a "gap between what citizens have expected and what the EU could do in terms of health".

Turning to Jens Spahn (above) for a moment, he recently presented the German Council presidency's health plans at the



informal Health Council, with his ambitions for a “health NATO” a key factor - especially in respect of the health budget.

European Innovation Scoreboard

Busy as you undoubtedly are, if you get the opportunity, it may well be worth taking a look at the European Commission’s Innovation Scoreboard.

Innovation is certainly something Europe is generally great at - although it does vary across Member States and the implementation could certainly be better.

Obviously, it’s of key interest to EAPM and its members and partners, not least because innovation in healthcare is something we continuously work hard to promote and encourage.

The link for the site can be found [HERE](#), but here’s a general idea of what to expect.

The annual EIS provides a comparative assessment of research and innovation performance in EU Member States, other European countries, and our regional neighbours.

Its aim is to let policy-makers assess relative strengths and weaknesses of national research and innovation systems, track progress, and identify priority areas to boost innovation performance.

The EIS covers the EU-27 plus Iceland, Israel, Montenegro, North Macedonia, Norway, Serbia, Switzerland, Turkey, Ukraine and the UK. It also looks at a limited number of global indicators from, for example, Australia, Brazil, Canada, China, India, Japan, the Russian Federation, South Africa, South Korea, and the US.

Currently, based on scores for 27 separate indicators, including

innovation activities in companies, investment in research and innovation, and human resource and employment elements, EU countries fall into four performance groups:

Innovation leaders are Denmark, Finland, Luxembourg, the Netherlands, and Sweden, all of whom perform significantly above the EU average;

Strong innovators are Austria, Belgium, Estonia, France, Germany, Ireland, and Portugal, all of which perform above or close to the EU average;

Moderate innovators are Croatia, Cyprus, Czech Republic, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Slovakia, Slovenia, and Spain. These countries show an innovation performance below the EU average;

And modest innovators - which is putting it gently - are Bulgaria and Romania. Both countries come in below 50% of the EU average.

The EIS 2020 shows an improved overall innovation performance. For the EU as a whole, it increased by 8.9% between 2018 and 2019. Over the same period, the performance improved for 24 Member States, most notably for Lithuania, Malta, Latvia, Portugal and Greece, where the innovation performance grew by more than 20%.

Compared to the last year’s edition, performance has improved for 25 Member States, most notably for Cyprus, Spain, and Finland.

There’s plenty of more specific sector information online at the link above, so do take a look if you’ve the opportunity.



World Health Organization

APPs the way to do it

Amid news that the UK's bluetooth track and trace app is to be ditched and swapped (it's not the only nation, by any means, that has found that it doesn't work particularly well), Germany has gone ahead with its own national app to trace interactions between smartphone users and track potential infections with the coronavirus.

Chancellor Merkel's chief of staff Helge Braun said: "The app we're presenting today is unique," although like the Brit version it also uses short-range Bluetooth signals.

It is, however, "very secure" from a privacy point of view (which is more than we can say for many of them), and is totally voluntary.

Lars Lensdorf, who's a partner at law firm Covington and Burling's Frankfurt office, said: "Nobody can force you to download the app," including an employer or a restaurant that you may visit.

His colleague at the firm, **Moritz Hüsch**, noted that consent is continually required, even for example, when inputting a coronavirus test result.

Meanwhile, in France, it turns out that its own 'StopCovid' tracing app may not be able to connect with others across the EU due to it storing data centrally,

European Commission Vice President **Margrethe Vestager** told the French parliament at the end of June: "It's somewhat more tricky to develop the technical standards for interoperability between decentralised systems, as I think will be the general rule, and the centralised system that France has been aiming for"

As mentioned earlier, Britain is not alone in having big issues with these coronavirus apps. For example, Norway paused its own app after only 14% of the population had signed up, and privacy campaigners just about everywhere you look have been warning against potential government surveillance of health data through dedicated devices.

Concerns are also rife among security professionals, while the

developers of the app being used in Italy have said that there is a high likelihood of both false positives and negatives.

As it stands, the UK is relying on citizens heavily, by asking them to conduct 'contact tracing', or calling those infected with the virus to determine whom they have been in contact with.

Unfortunately, many people are either failing to answer the tracers' calls or declining to give details.

Progress - and lessons learned

We mentioned in a recent update that the HTA discussions in Council have taken a hit from for the COVID-19 crisis, yet in France at least, this is apparently not the case.

Its Haute Autorité de Santé (HAS) claims that COVID-19 has "hampered neither the arrival of [innovative medicines] on the market, nor their evaluation by the HAS".

It seems that manufacturers are using the new fast-tracking applications from HAS more often, with 22 applications filed this year so far, compared to 16 in the entirety of last year.

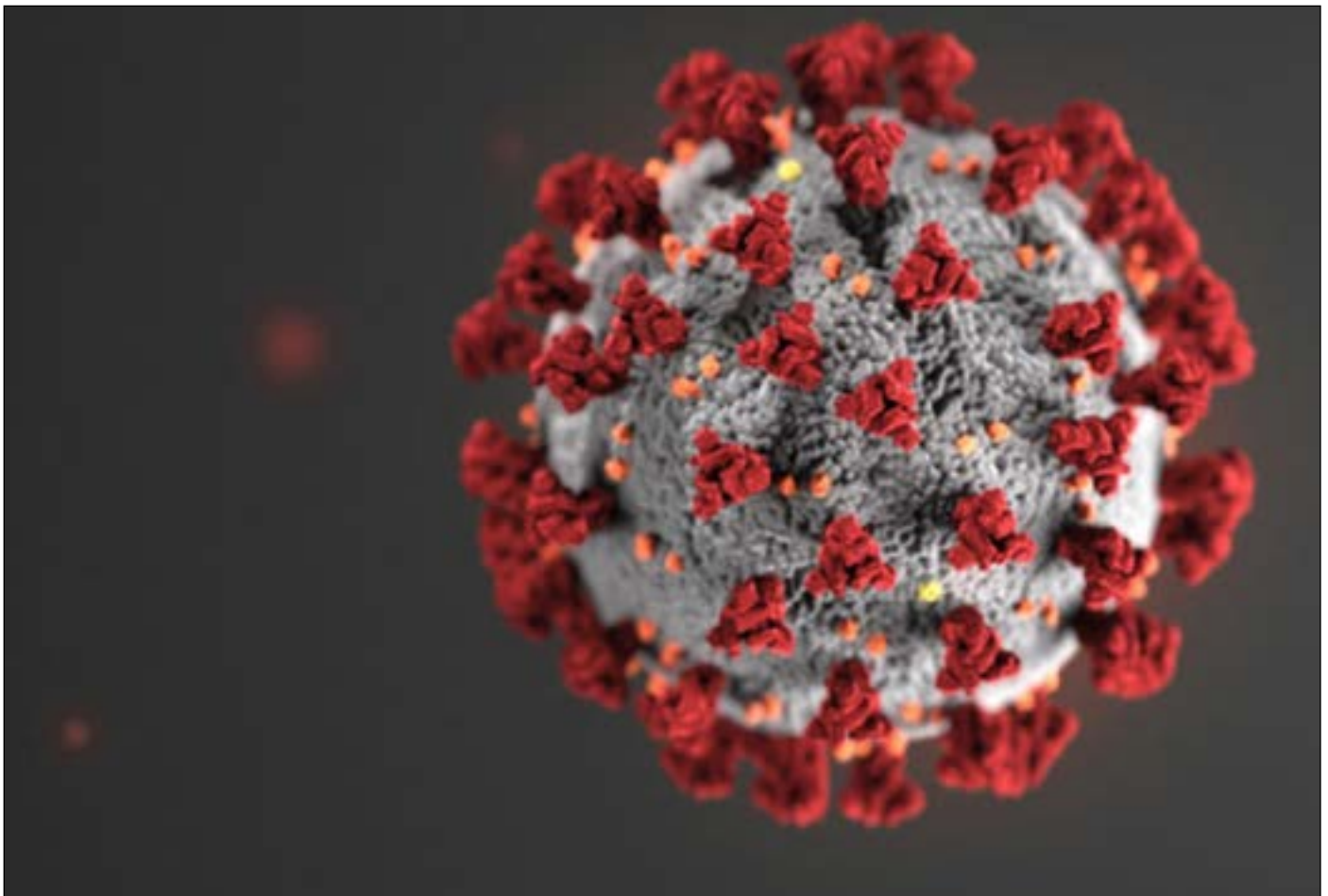
HAS says it is also writing opinions more quickly. Good to know.

Meanwhile, generics lobby Medicines for Europe has brought out a new paper on the lessons learned from the COVID-19 pandemic in Europe.

It seems that many of the shortcomings came from within the EU, with the biggest issue being the countries' unilateral actions. For example, slamming shut borders within the bloc caused supply issues, and hoarding.

The EMA couldn't deal with the dramatic increase in demand for ICU medicines, while the ECDC was slow to share epidemic forecasts, which didn't help medicines producers with predictions.

The upshot is that Medicine for Europe has now called on on the Commission to create an EU pandemic preparedness plan so Europe won't have to face the same obstacles in future.



For example, it has suggested diversifying supply chains and changing reimbursement and procurement policies, more regulatory flexibility, and more digital reporting.

Coronavirus trials on humans

The UK's Imperial College has begun clinical trials of its coronavirus vaccine candidate. The self-amplifying RNA vaccine is the second vaccine to be tested in tBritain, and has received £41 million from government and another £5 million from philanthropic donations.

Meanwhile, let's take a quick look at the Trials@Home project, which is backed by the EU/EFPIA Innovative Medicines Initiative.

The team behind the **Trials@Home** idea says it hopes the scheme can provide benefits to both organisers, who will have access to a broader patient pool, and patients who will be less inconvenienced.

Its project coordinator **Diederick Grobbee** says centralised clinical trials have an average drop-out rate of some 30%. However, in decentralised trials, participants spread throughout one or more countries could use technology to communicate; have their vital signs recorded; and get medication delivered to their homes or local pharmacy.

The project is looking to create a set of best practices, was well as letting Trials@Home carry out a decentralised study in a number of European countries looking at diabetes.

Just how lethal is COVID-19?

That's a good question.

A letter sent recently by prominent virologists and epidemiologists that maintains the coronavirus has mutated to become less dangerous has raised eyebrows, to say the least.

In fact, it sparked a dispute in the Italian scientific community, according to newspaper *Il Corriere della Sera*.

Those who disagree with the letter's authors say that any decreased lethality is purely a result of the efficacy of the lock-down and distancing measures. Experts in the technical-scientific committee advising the government also say this.

Meanwhile, *The Lancet* medical journal has published a study that estimates that 22% of the global population - which equates to 1.7 billion people - has an underlying condition that puts them at a higher risk of COVID-19 infection.

Such conditions are most common in countries with older populations; African nations with a high prevalence of HIV/AIDS; and small island countries with high numbers of patients with diabetes.

Andrew Clark, of the London School of Hygiene & Tropical Medicine, said of the study: "We hope our estimates will provide useful starting points for designing measures to protect those at increased risk of severe disease."

Further research meanwhile, shows that people suffering from obesity and related conditions such as type 2 diabetes and hypertension are also particularly vulnerable to this virus.



And a third study - this time commissioned by the World Health Organisation - has come under attack from scientists.

Its topic is optimal distancing measures to reduce coronavirus transmission rates, and states that reducing minimum distance requirements between people to one metre from two raises the risk of infection only slightly.

But **David Spiegelhalter**, a statistician from Cambridge, as well as others, has questioned its reliability. - just as UK Chancellor **Rishi Sunak** said that the government is reviewing the two-metre rule currently in force in the country.

So remain careful, and stay safe.

In the news

Take a look at some of EAPM's recent articles, below...

[EU rallies round WHO as Trump pulls plug](#)

[Governments battle tech firms over Coronavirus](#)

[Health means wealth – and we need both!](#)

[Lockdowns ease – but big worries remain for healthcare](#)

[EU health budget talks continue against #COVID-19 backdrop](#)

[Seychell swaps DGs as Commission stays busy, busy, busy](#)

[HTA delays, post-COVID treatment...and those apps](#)



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About EAPM

The European Alliance for Personalised Medicine was launched in March 2012, with the aim of improving patient care by speeding development, delivery and uptake of personalised medicine and earlier diagnostics, through consensus.

EAPM began as a response to the need for a wider understanding of priorities in personalised medicine and a more integrated approach among stakeholders. It continues to fulfil that role, often via regular major events and media interaction.

Our stakeholders focus not just on the delivery of the right treatment for the right patient at the right time, but also on the right preventative measures to ensure reliable and sustainable healthcare.

The mix of EAPM members and its broader outreach 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, and our engagement with MEPs and Member State health ministries in key policy areas is a crucial part of our ongoing work.

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