



# European Alliance for Personalised Medicine

EAPM Bulletin: Issue 58, January 2020

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

## EAPM looking ahead with 2020 vision

Greetings all, and an early happy new year from all at EAPM.

Hopefully, you're will all be properly rested after the well-deserved holiday period ahead - coming on the back of yet another busy year. 2020 promises to be just as lively!

Among the many achievements of the Alliance over the past 12 months was the publication of a multi-stakeholder survey, undertaken over three months in 2019.

The survey explores the potential, and the challenges that stand in the way of mobilising health data for wider health benefits, and also takes in the existence and potential of AI.

Its title is '*Cooperating on data – the missing element in bringing real innovation to Europe's healthcare systems*'.

The full survey can be found [here](#), but below are some of the key findings in bite-sized form:

Huge increases in computing power and new technologies have brought down the price of using Big Data in healthcare. But other aspects need to be optimised. Sharing is key.

However, effective data interpretation requires the rapid involvement of experts and organisations everywhere. And, crucially, policymakers.

The hurdles of healthcare data fragmentation, representation and organisational boundaries will need to be tackled for innovation in the field to succeed.

A further barrier to access to innovative personalised medicine is a lack of pricing contracts that are sufficiently flexible that they can account for clinical uncertainty. Budget impact and affordability remain key challenges for personalised medicine.

Manufacturers and payers need to find ways to ensure that value assessments lead to prices negotiations that reward valuable innovations whilst ensuring that patients can access new medicines and can afford to pay for them.

Also, there is currently a lack of information on testing methods and a lack of clear data on diagnostic uptake, as well as poor oversight of the performance of laboratories.

On the plus side, the new availability of data offers tools that would allow Europe's huge investments in health to be far better spent, by being properly targeted. The result would be much better health for far more Europeans.

### In the EAPM pipeline:

- **15 March: 5th International Forum on Personalised Medicine, Warsaw**
- **24-25 March: EAPM Croatia Presidency Conference, Brussels**
- **11-14 June: EHA congress, Frankfurt**
- **30 June: EAPM Presidency Bridging Conference, Brussels**
- **18-22 September: ESMO Congress, Madrid**
- **17-18 November: EAPM German Presidency Conference, Brussels**

But that requires a step that most European policymakers have not been ready to take. They need to cooperate, so that the data can be shared, and its full value realised.

Realistically, we cannot assume that all Member States and regions will have the same capacity and resources, and thus ways need to be found to maximise what already exists and look at enhancement possibilities.

How the data is collected and how its quality can be assured are also issues that need to be decided.

### ***So, what else did the survey discover? Here's a snapshot...***

The responses demonstrated a widespread genuine will to promote research and innovation, and its take-up, for the betterment of healthcare.

There was strong appreciation of the merits of data sharing, and readiness – under the right circumstances – to share personal health data for research purposes, and to undergo genetic sequencing.

Respondents highlighted their own differing views of the provision – or lack of it - for exploiting data in research, ranging from accusations of inadequate infrastructure or insufficient tools, to institutional reluctance over data sharing or information



## Keywords

Artificial intelligence · Big data · Regulatory framework · Member States · Systems · Enablers · Innovation · Commission · European Union · Genomics · Machine learning · Information and communication technology · Digital health · Personalised medicine · Precision medicine · Personalised healthcare · Diagnostics · Information · Value ·

Examples around us include using a virtual assistant to organise things, self-driving vehicles, and suggestions from a phone in respect of maybe a restaurant you might enjoy, a song you might like, plus voice and face recognition and so on.

Advanced robots can use AI, as can 'internet of things' apps, drones and, of course, AI can be used in healthcare.

The field is already a large one and is predicted to grow phenomenally quickly in the next decade, and it is not exaggerating to say that AI is going to change our world.

The promise has nowhere near been fulfilled yet, and new applications will come along one-after-the-other. Therefore, the opportunities for Europe are huge. But the EU and Member States need a solid framework as the competition globally is, and will be, just as huge.

In this sense, the EU needs to be better prepared if we are to keep up, let alone take a lead, in the context of AI and its promise. A coordinated approach is certainly required, especially as we already have brilliant researchers, excellent laboratories, forward-looking entrepreneurs, and strength in robotics.

### ***What emerged from the survey is briefly as follows:***

Europe's goal should be integrating AI into Europe's health-related operations to improve clinical care, drive innovative therapies and treatments, and make healthcare systems more efficient.

The EU needs to be better prepared if Europe is to keep up, let alone take a lead, in the context of AI and its promise. A coordinated approach is required, to fully utilise brilliant researchers, excellent laboratories, forward-looking entrepreneurs, and strength in robotics.

The full benefits of AI in healthcare depend on addressing challenges ranging from access to data and regulatory and technical issues to still-unresolved legal and ethical questions.

Organisations should embrace risk-based accountability ap-

proaches, putting in place technical or organisational measures, such as product development life-cycles and ethics review boards, to minimise risks.

The EU needs to commit resources to the development and adoption of AI and promoting its use, through testing innovative solutions in healthcare settings.

Europe needs a broad uptake of AI in the economy, and here the role of start-ups and small to medium-sized enterprises (SMEs) is pivotal, both in terms of its scale and its vitality.

European initiatives to build voluntary ethics guidelines for AI in healthcare are welcome, as these would help set world standards for AI, and simultaneously give the reassurance needed to society to trust these technologies as well as for industry to invest further.

The EU needs to position itself so as to play a leading role in the adoption of standards, so as to influence the emergence of the same on a global scale.

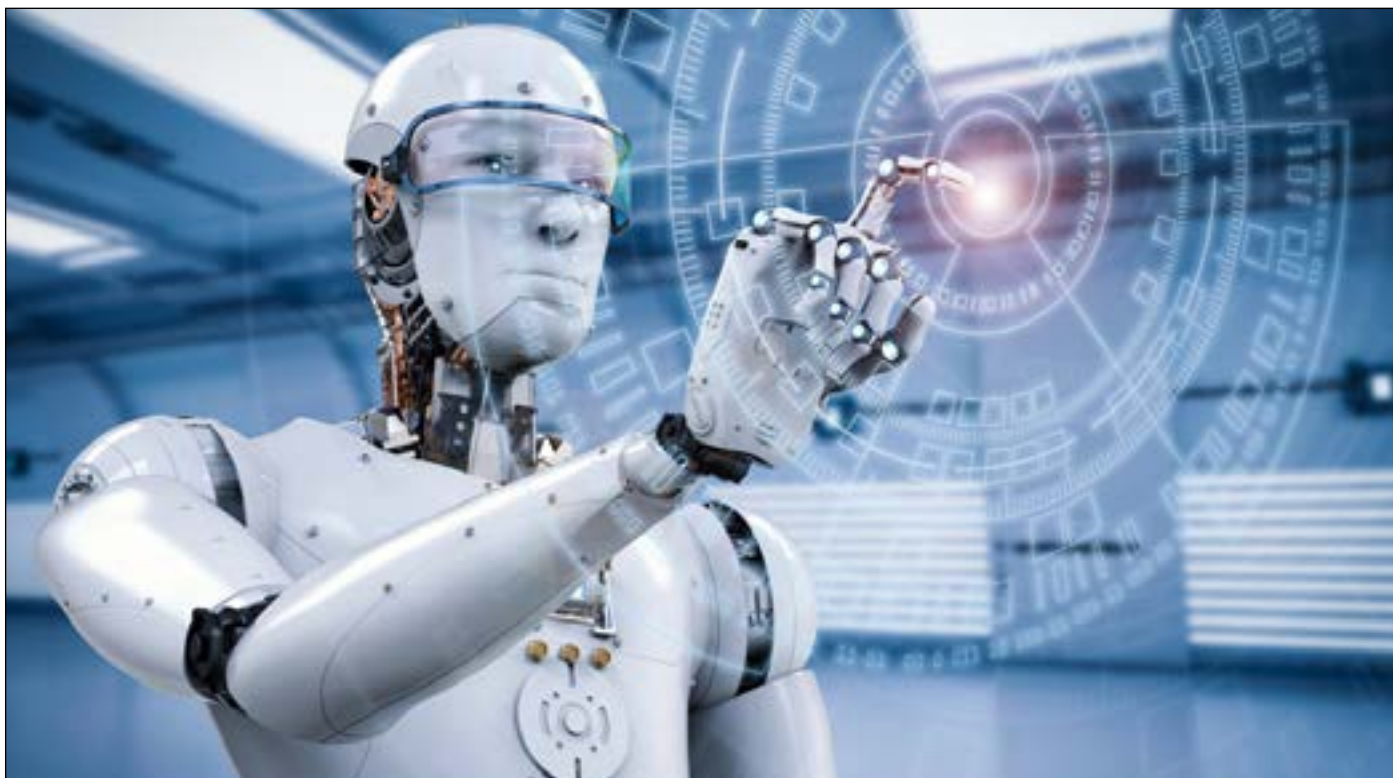
The ultimate goal in respect of data sharing should be creating EU-wide common data spaces that promote access to health data in a secure environment, with 100% of health data digitised as soon as possible and with maximum interoperability.

A further objective is to maximise the benefits of AI for all Europeans by fostering the development of trusted AI that corresponds to European ethical values and citizens' aspirations, and to ensure cooperation among industry and academia in collaborative R&D and innovation

### ***To do all this we need the following...***

Successful adoption of AI for healthcare requires multi-stakeholder commitment to address the opportunities and the challenges. Europe has still to maximise its potential in this domain, with investment lagging behind other major global regions in the world.

It is also behind on ICT skills. Almost all Member States are



facing shortages of ICT professionals, including in the area of AI. This is not good enough and needs to be addressed quickly.

Europe stands on the brink of a huge success - the prize is within reach. If it manages to seize the opportunity that AI presents for healthcare, it can improve life for its citizens, make better use of its healthcare budgets, and enhance its competitiveness in a sector that will dominate global growth for a generation.

#### **Data sharing, front and centre**

Europe is currently proving that it is capable of working together and sharing, despite opposition to some of the mandatory aspects to the Commission's plans on HTA, as the enthusiasm resulting from what was originally named the MEGA initiative (standing for Million European Genomes Alliance and proposed by the European Alliance for Personalised Medicine), now renamed as 1MG, has clearly demonstrated.

There is a clear willingness on the part of many Member States, and the regions within them, to collaborate when it comes to data sharing in healthcare, and not just in genomics.

As a little background, on the 10th of April 2018 during the European Commission's Digital Day 2, a declaration on linking genomic databases across borders was signed by a swathe of Member States, and many more have joined since. This Declaration has the title "*Towards access of at least 1 million sequenced genomes in the EU by 2022*".

MEGA+ is a response to this willingness and, now, the MEGA+ initiative extends this process to all medical data, not just genomes, but to include imaging, eHealth apps, electronic health records, and more, all undertaken with the highest level of ethics and patient consent.

AI will allow us to make good use of big data in health. With AI, it is possible for systems to read unstructured data, identifying meaningful relationships in raw data, aggregating and displaying it, and offering analysis.

By unlocking complex and varied data sets to develop new insights, AI can help physicians and researchers prevent disease, speed recovery and save lives. It can speed genomics processing, aid in the development of advanced drugs and therapies, and contribute to more accurate personalised treatment.

*Here's the [link](#) to the survey once again.*

#### **Digital health festive quiz**

During the final European Parliament plenary of 2019 held in Strasbourg, MEPs quizzed the European Commission about how it plans to bring about the rapid digital transformation of health in Europe.

EU Health Commissioner Stella Kyriakides was set to face four questions on Brussels plans to train healthcare professionals and citizens with respect to digital skills, and on how it will guarantee patient confidentiality.

As we know, the Commission wants to bring about a rapid digital transformation of health and care at European level, and has outlined the changes required in this respect in healthcare across Member States.

The Commission is highlighting disease prevention, early detection and diagnosis, treatment, care and follow-up. On top of this comes targeted research, training of HCPs, and the provision of information to patients.

#### **MEPs want to know:**

What is the Commission planning to do to ensure that healthcare professionals are qualified and equipped with the appropriate digital skills? Equally important, how does the Commission intend to help Member States and regions in disseminating the knowledge and skills needed by citizens and patients who use digital healthcare solutions?

At each stage of the process how does the Commission intend to guarantee patient confidentiality? How will it guarantee the



security and independence of eHealth and mHealth software solutions and connected objects?

Does the Commission agree that people must remain the central concern of in the changes to healthcare brought about by the digital revolution?

What actions does the Commission intend to take to ensure that patients have secure access to their data and to information on the decision-making process of healthcare professionals on therapeutic choices, treatment and care?

## More data on data

The Commission will come out with a data strategy by the end of 2020, which will include health data, according to health chief **Stella Kyriakides**.

She was reminded by MEPs at the recent Strasbourg plenary that Europe needs to protect people's personal health data, must ensure that digital health systems are interoperable, and the duty not to leave people behind when it comes to digital skills.

In the **Czech Republic**, meanwhile, things are zinging along with regards to e-prescriptions. Penetration is around the 100% mark, according to the country's Health Minister **Adam Vojtěch**.

He added, though, that roadblocks to passing broader e-health legislation are among his biggest frustrations. But he did also predict that the completion of proposed measures for reimbursing innovative medicines and devices will be sorted by the end of January.

## Better safe

**Ireland** has published a patient safety bill that is designed to make it mandatory for serious patient safety issues to be openly disclosed, reports *Politico*.

Several external bodies will also to be notified of these incidents if the bill goes through parliament, and it would apply to both public and private health services.

## Medtech moves

The European Parliament has adopted 'corrigenda' to the new medtech regulations, which come in to force in 2020.

One extends the grace period to four years for low-risk devices with a higher-risk classification, after no one requested a formal vote in the plenary.

The way it was done is a little odd - with Parliament agreeing to use a procedure intended to correct typos to grant the reprieve

Once corrigenda go to MEPs, they actually don't need to vote. The corrections will now go to plenary - but there'll only be a vote if a political group asks for one.

Despite this speeded-up process, it's all a bit too little too late for MEP **Biljana Borzan**, who said: "It's a really silly situation that we started to work on this legislation in 2012 and we are now running out of time."

Meanwhile, it seems that national medtech regulators are annoyed with news that the improved Eudamed database envisioned under the incoming regs is set to be delayed by two years.

An open letter from the executive group for the Competent Authorities for Medical Devices read: "The alternative is a set of heavily burdensome administrative transitional solutions."

They argue that the Commission's solutions focus on the "most precise legal interpretation possible rather than operational effectiveness of implementation."

## Brexit. Yes, that again

The UK's Prime Minister **Boris Johnson**, fresh from a pretty stunning election victory, will diverge from EU trade rules once the UK leaves, says former Brexit Secretary **David Davis**. This will especially be the case in emerging industries.

Davis told the BBC's *'Today'* programme that the prime minister would use his new 80-seat majority to push this through.



Hrvatsko predsjedanje  
Croatian Presidency of the  
Vijećem Europske unije  
Council of the European Union

"The negotiating hand Boris has is much stronger, that is just an objective fact. The second objective fact is that Boris himself does want to diverge," said the ex-Cabinet Minister, who resigned in protest at **Theresa May's** original deal - which many argue was a whole heap better than the one Boris has in place.

## No laughing matter

**Denmark's** health ministry has flagged-up the increasing use of nitrous oxide - aka laughing gas - among young people aged 15-25.

It called the results of a survey carried out among 32,000 young people "serious", noting that 17% of those polled said they had used nitrous oxide cartridges recently.

The health ministry noted that laughing gas is usually produced for industrial purposes, rather than human consumption, and could lead to "serious health consequences". These include oxygen deficiency and death.

## Triple-presidency conferences: Forward as one into 2020

EAPM will be hosting three EU Presidency-themed conferences during 2020.

These will be, firstly, during the **Croatia Presidency**, followed by a bridging conference between the **Croatia and Germany** presidencies, and a final event while **Germany** is at the helm.

The Croatia conference will take place in Brussels from **24-25 March**.

Not only do these conferences reflect the nature of the relative presidency policies in the healthcare arena, but also act as major events during what will be the first full year of the two new legislative bodies - the Parliament and the Commission.

Croatia has already outlined four key priorities for its turn as EU President - a role it takes over as you read this.

While healthcare is not mentioned specifically, several issues will have an impact in that arena.

Croatian Prime Minister **Andrej Plenkovic** highlighted "a Europe that connects", and said that Croatia's four prioritised goals are a Europe that is growing and developing, a Europe that connects economically, energy-wise and infrastructure-wise, a Europe that protects and a Europe that is globally influential.

The prime minister stressed that a "Europe that connects" is needed and that it is therefore necessary to further develop transport, energy, and digital infrastructure.

"We will stand for a Europe that protects its citizens while respecting and protecting the rule of law," he said.

The Croatia presidency slogan is: "*A strong Europe in a challenging world*".

*Bridging conference - Croatia and Germany Presidencies  
Maintaining public trust in use of Big Data for health science*

*Brussels  
30 June 2020*

Personalised healthcare brings us the opportunity to put citizens at the heart of decision making, including talking openly about what happens to data, who is using it, and what level of control people can, or cannot, expect.

We can apply ethical rigour every time data is used, shared or transferred to safeguard individual privacy, and ensure data is secure and provide guarantees that data will not be compromised by breaches that reveal personal information.

We can ensure that the public has trust in data science, especially for large scale initiatives that enable significant breakthroughs in our understanding of human disease.



We can underpin public trust by advocating the value of health-data research to society and promote the need for robust, trustworthy and ethical approaches to deliver new health advances for our citizens.

Generally speaking, one of the great challenges to reduce both late-stage incidence and mortality is early diagnosis. But it has to be reliable. In this conference that bridges two Presidencies of the EU (Croatia and Germany), the emphasis is on public trust in health data and its uses.

One of the great opportunities to reduce both late stage incidence and mortality is early diagnosis. But it has to be reliable, of course.

*German Presidency conference: Building a decentralised, data-rich biomarker space to speed better cancer care*

*Brussels  
17-18 November 2020*

Looking ahead to the next two decades, there will be a massive increase in cases of cancer in Europe.

Regulators, industry and healthcare professionals really need to step up to this new reality, and this also applies to citizens, who have a certain degree of responsibility for their own healthcare.

Lifestyle changes will be paramount, and could amount in many cases to the best form of prevention.

Stopping smoking, cutting down on alcohol, getting off the sofa and exercising, eating the right food - it all helps. Adhering to medicine regimes isn't a bad plan either...

However, biomarkers have a job to do, too, in modern personalised medicine. We need more of these that are relevant to treatment.

Certainly, we're churning out lots of data, but as more clinical trials and large scale epidemiological studies take place, new technologies such as blockchain will be urgently needed to handle the data.

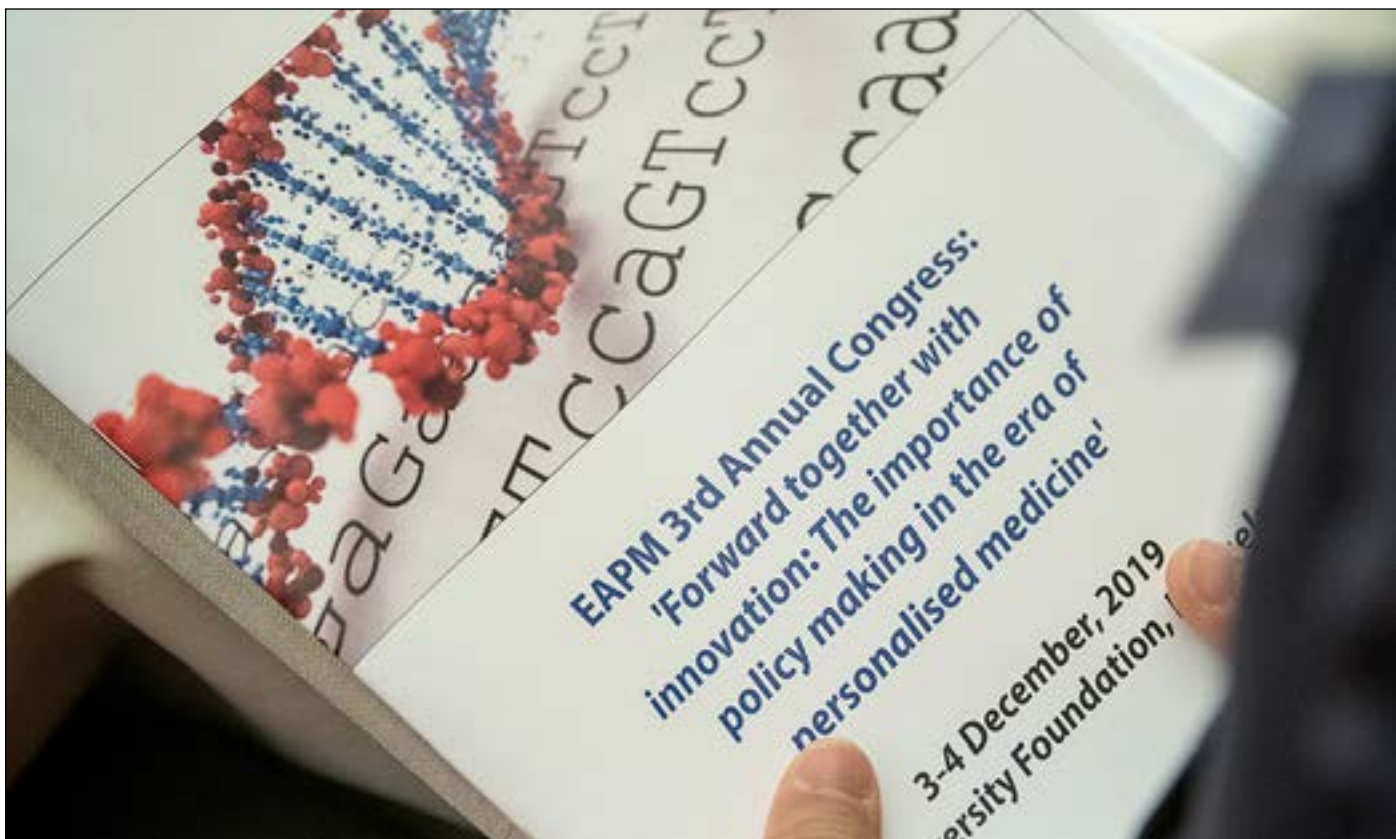
And this has to be done without infringing regulations surrounding data protection (namely the General Data Protection Regulation (GDPR)).

Unfortunately, the barriers in respect of data sharing mean that risks related to data security and privacy can have a paralysing effect on progress.

One of the goals of EAPM events is to engage politicians and lawmakers in the fast-growing field of personalised medicine, and deliver political asks through our consensus-based process, while also aiming to showcase developments and new ideas.

### **And finally...**

'It may be winter outside, but in my heart it's spring...' goes the song. Our good friend **Peter Liese** MEP was certainly noticeably



chirpy at our recent Annual Congress in Brussels, given that there was a good deal of pessimism ahead of the 2019 European elections that DG SANTE would be dismantled.

Not so, as it turned out. Peter said at our event: “We are now in a situation where the health agenda is really a priority for policymakers in Europe.”

The EAPM stalwart talked about the emphasis on cancer, adding that making registries comparable across the EU is a top priority. “We need to have a European approach here,” he said.

So far so good. But perhaps there ought to be a fairly swift meeting of the Commission regarding its very own, much touted Beating Cancer Plan. It’s not been added to the Executive’s the agenda between now and March...

## In the news

[Artificial Intelligence: Power for Civilisation – and for Better Healthcare](#)

[Cooperating on Data: The Missing Element in Bringing Real Innovation to Europe’s Healthcare Systems](#)

[EAPM 3rd Annual Congress report: 'Forward together with innovation: The importance of policy making in the era of personalised medicine'](#)

Follow EAPM on Twitter at [@eaupmbrussels](#)



## 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.**

**Contact: Denis Horgan  
EAPM Executive Director  
Avenue de l’Armee/Legerlaan 10, 1040 Brussels  
Tel: + 32 4725 35 104  
Website: [www.euapm.eu](http://www.euapm.eu)**