



# European Alliance for Personalised Medicine

EAPM Bulletin: Issue 72, April 2021

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## Next EAPM events

### April - June 2021:

Expert Panels on NGS/Biomarker Testing

### April - June, 2021:

Expert Panels on RWE/D

### July, 2021 :

Slovenia Presidency conference, 'RWE and Data Governance: Bridging Presidency conference, July 1st 2021 plus policy engagement'

***Welcome, health colleagues, to the European Alliance for Personalised Medicine (EAPM) March Newsletter - as ever, it has been a busy month for the EAPM, what with movements on COVID-19, an EU Presidency conference and work on the Europe Beating Cancer Plan - EAPM Executive Director Dr. Denis Horgan provides all your updates below, as usual.***

### **EU Presidency Conference**

EAPM's 9th EU Presidency Conference, under the auspices of the Portuguese EU Presidency, took place online on Monday, 8 March - the aim of the game was all about establishing a health policy framework across the EU. The conference featured a wide range of keynote speakers from across the EU, including Christine Chomienne, vice chairwoman of the Mission Board Cancer at the European Commission and professor of Cellular Biology at the Université de Paris, France and Daria Julkowska, co-ordinator of the European Joint Programme on Rare Diseases.

The European Union is recognizing the need to make better provision for health, and has started to put in place ambitious frameworks to remedy the deficiencies exposed by the COVID 19 pandemic and to create longer-term strategies for harnessing innovation in the quest for better care of its citizens. But the structures, for all their merits, are not enough.

As Denis Horgan, the executive director of EAPM, which organized the conference, put it: "There is an implementation gap in translating Europe's grand plans into concrete actions. It is necessary to set up mechanisms and investment and instruments that can deliver on the obvious potential."

In particular, given EAPM's core interest of furthering precision medicine, he suggested that the realisation of that promise depended heavily on the necessary elements being in place across the healthcare systems of Europe. Healthcare professionals, decision makers, patient organisations,

and European umbrella organizations representing interest groups and associations actively engaged in the field of personalised medicine took up the theme.

The themes undertaken by the conference included propelling health care through an effective governance framework, data developments, an update on the Europe Beating Cancer Plan and the role of biomarkers and advanced molecular diagnostics.

## Data Developments



Ceri Thompson, Deputy Head of Unit DG CNECT H3 in the European Commission, responsible for eHealth, Wellbeing and Ageing, listed the ambitions in digital health, with the upcoming Data Governance Act, Digital Market Act, Implementing Act for the Open Data Directive, and the Data Act – each scheduled to bring new advantages to the health sector. The European Health Data Space was scheduled to appear before the end of this year, and will be followed by a cascade of other initiatives, in cancer imaging, diagnostics and treatment, genomics, cybersecurity, and work on digital twins over the next five years, she added. She outlined the EU's four-pillar strategy for data access and use, with cross-sectoral governance, an enabling infrastructure, adequate skills and competences, and the roll-out of common European data spaces.

The conference sought to move towards establishing a policy framework, in order to realize the potential of personalised health care, and not only in Europe: Europe's engagement in global research and scientific enterprise can benefit the population of the entire planet.

The ambition of Commission President Ursula von der Leyen is a Europe that 'must lead the transition to a healthy planet and a new digital world'. And Health Commissioner Stella Kyriakides acknowledged that "European citizens expect the peace of mind that comes with access to healthcare... and protection against epidemics and diseases."

The second session of the conference dealt with the EU's Beating Cancer Plan, and the conference will examine the new technologies, research and innovation that the Cancer Plan is taking as a starting point, in terms of setting out a new EU approach to cancer prevention, treatment and care.

## Cancer care

Solange Peters, Chair of Medical Oncology at Lausanne University, spelled out how ESMO (of which she is currently President) is contributing to the EU's Beating Cancer Plan, with its goal of marshalling technologies, research and innovation into cancer prevention, treatment and care along the entire disease pathway. It is a whole-of-government approach that focuses on the patient and maximises the potential of new technologies and insights; strengthens co-operation and opportunities for EU added value, eradicates inequalities in access to cancer knowledge, prevention, diagnosis and care, and delivers improved health outcomes to patients. Christine Chomienne, Vice-Chair of the Mission Board Cancer at the European Commission and Professor of Cellular Biology at the Université de Paris,

described the joint work of the Cancer Mission as “an unprecedented level of cooperation.” Everyone - from newborn babies to the elderly, from sufferers from chronic disease to acute cancer patients, and from health ministries to funding agencies - stands to gain. The price is nothing more than a shift in policy. The prize - in terms of value to the economy and to lives - is priceless.

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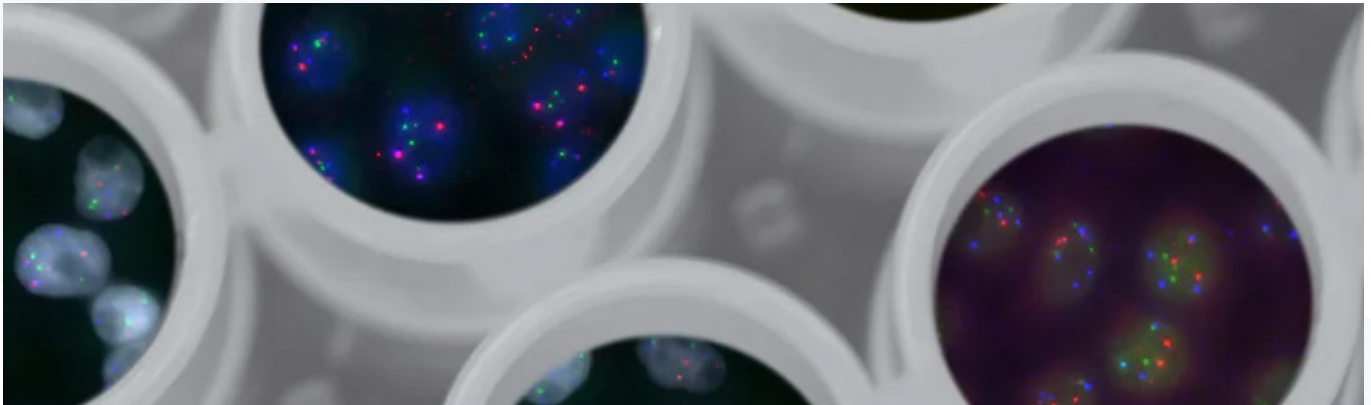
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**And here is the full link to the conference article -**

<https://www.eureporter.co/health/personalised-medicine/european-alliance-for-personalised-medicine-personalised-medicine/2021/03/11/europes-scaffolding-for-health-care-is-ambitious-but-now-it-needs-the-construction-to-be-completed/>

## Multistakeholder engagement



Close collaboration across national borders and reciprocal consultation with stakeholders have to be at the very centre of systemizing the contribution of genomic data to the development of personalised medicine. How to achieve this was the focus of discussion at the virtual kick-off conference with stakeholders of the European plan to improve citizens’ health and boost medical research with the Beyond 1 Million Genomes project.

The European 1+ Million Genomes (1+MG) initiative is the EU’s answer to some of the most pressing challenges in developing the potential of genomics more fully. The insights that genomics offers are not only transforming approaches to medical research; they are also increasingly enriching clinical operations and informing personalized medicine.

But exploiting the ability of genomics to deliver earlier diagnosis, more effective prevention programmes and more precise targeting of therapies depends crucially on data. To capture the full benefits of genomic data, it must be shared with multiple actors: researchers to support academic and clinical research; health providers to support delivery of health services and public health

activities; and commercial organizations involved in developing and implementing new health technologies or delivering health care services. This in turn raises numerous logistical questions about data acquisition and exchange, and important ethical, social and legal issues (ELSI) relating to the treatment of data.

In these conspicuously sensitive areas, there is a definitive need for developing wider links across the healthcare community, for careful development of the necessary mechanisms and safeguards, and for achieving the right balance in generating common approaches across borders while still respecting national, local and private interests.

**And here is the link to the full article on multi-stakeholder engagement -**

<https://www.eureporter.co/health/personalised-medicine/european-alliance-for-personalised-medicine-personalised-medicine/2021/03/15/master-multi-stakeholder-collaboration-and-it-will-be-possible-for-the-eu-to-master-genomic-data-sharing/>

## Member State position in relation to the EU Cancer Plan

**Portuguese EU Presidency:** Portugal holds the EU Presidency at present, until the end of June – and at the recent informal video conference of 16 March concerning Europe’s Beating Cancer Plan, the member state indicated that the pandemic had had an impact on the EU’s attempts to combat cancer, which is the second leading cause of mortality in the EU behind cardiovascular diseases. As far as Portugal is concerned, the four key action areas are prevention, diagnosis, treatment and aftercare, adding that the debate would be steered by two questions that covered the long-term sustainability of the proposed measures in the cancer plan and how the plan would take into consideration the different starting points of member states.

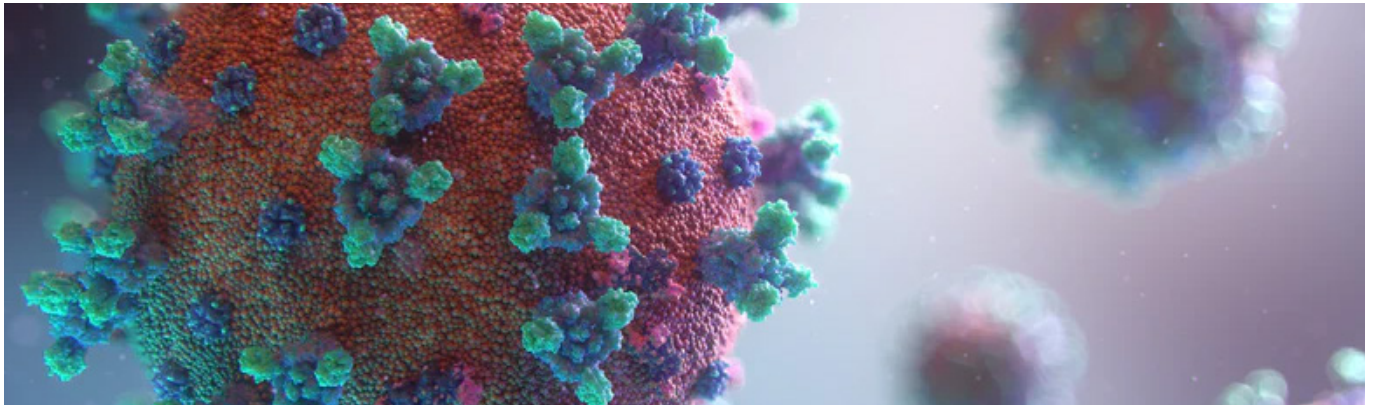
**Slovenia EU Presidency:** Slovenia will hold the EU Presidency from the beginning of July to end of December 2021 – during the conference, Slovenia indicated it was pleased the Cancer Plan was on the agenda and welcomed the ambitious plan, and indicated that Slovenia was drafting its third cancer plan in order to ensure long-term sustainability. It was added that the Commission working plan would need specific guidelines, and that the Cancer Plan was an important step towards an EU health union.

**France:** France indicated that the plan was in line with the country’s own, and there were a number of synergies. Combating tobacco use and the drinking of alcohol whilst promoting exercise would be important, and that the country wanted to see 1 million more screenings by 2025. France also welcomed the plan by the Commission to set up an implementation group in order for MS to be as involved as possible with the decision making process. They also highlighted the key role of existing groups with particular reference to the European Parliament special committee.

**Spain:** Spain welcomed the EU cancer plan and noted that they had recently updated their national cancer strategy, citing progress in early detection, strengthening health promotion, and a focus on health care in childcare and adolescence. Spain indicated that a clear way to make progress together would be the cancer inequalities register. Monitoring social determinants would be crucial and increased co-operation between member states would be needed - as well as work at a technical level via existing groups co-operation at the political level would also be needed.

## In other news...

### Coronavirus cases on rise across Europe



Analysis has found that cases of coronavirus are rising in three-quarters of European countries, with the highest increases happening in central and eastern Europe. Only nine of the 40 European countries analysed recorded fewer cases in the first week of March than they did in mid-February, with Portugal, Spain and the UK registering the largest drops. Spain is the only country that has a lower case rate than it did at the end of September.

### EU health programme ‘more than a reaction to the pandemic’

The European Parliament has voted through the new 5.1 billion EU health programme, EU4Health, with 631 votes in favour, 32 against and 34 abstentions. The programme was put together in the thick of the COVID-19 crisis, but it is “more than a reaction to the pandemic”, said EU Health Commissioner Stella Kyriakides, addressing the MEPs in a debate. “With the EU4Health programme, we have the tools at hand to make long-lasting changes,” she said. EU4Health will be a key instrument in the EU’s fight against cancer, addressing lack of screening, early diagnosis and access to treatment. It will also help digitize health care and support the creation of the EU health data space, allowing open sharing of health data. Its medium-term goals include reducing health inequality in Europe. At 5.1 billion, EU4Health will be twelve times larger than its predecessor, underlining the extent to which the pandemic has moved health up the EU agenda.

### Commission to propose digital green pass for travel

The European Commission presented a legislative proposal for a Digital Green Pass on 17 March. The certificate is intended to contain proof that a person has been vaccinated, results of tests for those who couldn’t get a vaccine yet and may also consider recovery from COVID-19. The Digital Green Pass is aimed at enabling the safe movement of people across the European Union, or further afield.

And the European Parliament voted on Thursday (25 March) to expedite the Commission’s EU-wide travel certificate. The proposal got a further push after the meeting of EU leaders Thursday night, when they issued a statement noting that “legislative and technical work on COVID-19 interoperable and non-discriminatory digital certificates, based on the Commission proposal, should be taken forward as a matter of urgency”.

### Commission to propose digital green pass for travel

The European Union will fast track approvals of coronavirus vaccines adapted to combat mutations, Health Commissioner Stella Kyriakides has said. “We have now decided that a vaccine that has been improved by the manufacturer on the basis of the previous vaccine to combat new mutations no longer has to go through the entire approval process. So it will be faster to have suitable vaccines available without compromising on safety.”

## EU leaders face coronavirus 'fatigue'



Despite the slow vaccine rollout in Europe, delayed by almost a month compared to former member the UK, Commission President Ursula von der Leyen said the bloc still aims to inoculate 70% of all adults — around 255 million people — by September. “This is a goal that we are confident we will reach,” she said.

EU leaders were also updated on the movement of fast spreading new variants of the virus within Europe, with the so called U.K variant now present in 26 member countries. The variant first detected in South Africa has been identified in 14, while the Brazilian type is known to be in seven. This means that restrictions could well continue through coming months. “There is a growing COVID fatigue among our citizens. It has been a very trying year, but we should not let up now,” said von der Leyen.

### Choosing better lung cancer treatments with machine learning

Researchers say that machine learning could help guide healthcare workers' treatment decisions for lung cancer patients after developing a model that is 71% more accurate at predicting survival expectancy of patients. A team of Penn State Great Valley researchers conducted a study in which they developed a deep learning model that is more than 71% accurate in predicting survival expectancy of lung cancer patients, which is significantly better than traditional machine learning models that the team tested which have around a 61% accuracy rate. Deep learning is a type of machine learning that is based on artificial neural networks, which are generally modelled on how the human brain's own neural network functions.

### EMA aims to keep public up to date



The European Medicines Agency (EMA) is making every effort to ensure its expert opinion on COVID-19 vaccines is heard among EU citizens. On 26 March, the agency today hosts its third public meeting to update people (virtually) on the assessments and approvals of new vaccines, as well as the safety monitoring of those on the market. The event will be broadcast live from 13h.

## Coronavirus: EU stops short of vaccine export ban

European Union leaders have stopped short of banning vaccine exports after a protracted row with the Anglo-Swedish manufacturer AstraZeneca.

At a summit on Thursday (25 March) they gave backing in principle for toughening export controls. But a post-summit statement emphasised the importance of global supply chains needed to produce vaccinations.

Elements of the AstraZeneca vaccination are manufactured in a number of EU states. European Commission President Ursula von der Leyen said AstraZeneca must “catch up” on deliveries to the EU before exporting doses elsewhere.

French President Emmanuel Macron told reporters this marked “the end of naivety” from the EU. Vaccine rollouts in EU states have started sluggishly, and the bloc has blamed pharmaceutical companies - primarily AstraZeneca - for not delivering promised doses. AstraZeneca has denied that it is failing to honour its contract.

“I think it is clear that first of all the company has to catch up,” Mrs von der Leyen told a news conference after the virtual leaders’ summit.

“It has to honour the contract it has with European member states before it can engage again in exporting vaccines,” she said. “We want to explain to our European citizens that they can get their fair share.”

The EU was accused, primarily by the UK and the World Health Organization (WHO), of so-called vaccine nationalism after it introduced export controls on jabs produced within the bloc. In response, UK Prime Minister Boris Johnson warned that “blockades” were not “sensible”. He said a ban would imperil the UK’s vaccination drive, which has so far been more successful than EU member states’ vaccine programmes.

Mr Johnson also warned that a ban that extended beyond AstraZeneca’s disputed supply could also block jabs produced for BioNTech/Pfizer in Belgium.

But Mrs von der Leyen hit back on Thursday, arguing the EU was the “region that exports most vaccines worldwide”.

“We invite others to match our openness,” she said.

## Conference on strengthening the role of the EU in global health

On 25 March, under the scope of the Portuguese EU Presidency, a conference was held on reinforcing the role of the European Union in global health. More than 30 speakers, including leaders, political decision-makers, experts and representatives of European institutions, looked at topics such as global health during a pandemic, strategic EU-Africa alliances, particularly regarding access to vaccines, and the promotion of universal health coverage. The conference, whose opening session was hosted by Portuguese Health Minister Marta Temido, also saw State Minister for Foreign Affairs Augusto Santos Silva attend.

With many countries in the world only just beginning their vaccination campaigns — or in some cases, waiting for the arrival of their first jabs — the EU has attempted to allay fears that it’s focused only on the vaccination of Europeans.

Commission President Ursula von der Leyen pointed to the EU's integral role in the ACT-Accelerator (ACT-A), which is aimed at equitable access to vaccines, treatments and tests, as well as the 2.2 billion contribution to COVAX, which is part of ACT-A, by the EU and its member states.

"If only the people in Europe are vaccinated, this does not help much," she said. "That's why our commitment goes well beyond Europe's borders. We are exploring solutions to scale up the manufacturing capacity of vaccines inside Africa and the next European budget will invest in the capacity of health systems around the world."

Addressing the export spat head-on, Health Commissioner Stella Kyriakides said that openness was a "two-way street," but added that the move to tighten export controls wouldn't affect the bloc's contributions to COVAX.

While WHO chief Tedros Adhanom Ghebreyesus praised the EU's role in the pandemic response, he also pointed to the growing gap between vaccines administered in rich and poorer countries. "We need to ensure vaccines are a source of hope for all and not for some," he said.

The EU has pledged to share excess vaccine.

**We await further developments...Meanwhile, enjoy the newsletter, have an excellent weekend, stay safe and well, see you next week.**

## In the news...

### **Key health issues for the months ahead as member states work together:**

<https://www.eureporter.co/health/personalised-medicine/european-alliance-for-personalised-medicine-personalised-medicine/2021/03/23/eapm-key-health-issues-for-the-months-ahead-as-member-states-work-together/>

### **Looking to the future with key health issues and co-operation under the microscope in COVID-19 era:**

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### **Europe's scaffolding for health care is ambitious - but now it needs the construction to be completed:**

<https://www.eureporter.co/health/personalised-medicine/european-alliance-for-personalised-medicine-personalised-medicine/2021/03/11/europes-scaffolding-for-health-care-is-ambitious-but-now-it-needs-the-construction-to-be-completed/>

### **Master multi-stakeholder collaboration, and it will be possible for the EU to master genomic data sharing:**

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### **Talk is good, action is better on improving European health care:**

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