



# European Alliance for Personalised Medicine

EAPM Bulletin: Issue 68, November 2020

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## Next EAPM events

### 10 December 2020:

Screening for biggest cancer killer: Strategy on the way...

### November 2020:

EAPM: Cancer to dominate health issues during November – lung cancer awareness month

*Greetings to all health colleagues, and welcome to the European Alliance for Personalised Medicine (EAPM) November newsletter. The focus for the month ahead, which is lung cancer awareness month, will very much be on cancer, with the EU Beating Cancer Plan hitting its stride, and we will detail this during the newsletter, as well as the EU Health Data Space. Read on, and enjoy.*

### Lung cancer mortality grows during coronavirus...

As it is the world's leading cause of cancer-related morbidity and mortality, which is well documented globally, lung cancer (LC) awareness month could not have come at a more propitious time, particularly given the fact that cancer treatment efforts have taken an inevitable hit from the coronavirus pandemic, given that so many intensive care beds have been taken in response to COVID-19.

Lung cancer has more than 2 million new cases diagnosed annually, and its five-year survival rates are less than 20%. While improvements in outcomes are within reach, they are heavily dependent on early diagnosis and accurate staging – these permit rapid appropriate treatment and decreases the rate of advanced/metastatic disease.

In addition, according to recent reports, the first wave of the coronavirus outbreak has had a huge impact on UK lung cancer patients' survival and detection rates. A third of patients have died since the beginning of the pandemic, experts said. The UK Lung Cancer Coalition warned that "the catastrophe that is the COVID-19 pandemic" is likely to reverse improvements in survival rates made over the past 20 years. The report also stated: "GPs are likely to misdiagnose early lung cancer symptoms as COVID-19 because of the large number of COVID-19 cases." EAPM will be organizing an event on December 10th to discuss our recommendations.

### ...but EU Beating Cancer Plan on track

Health Commissioner Stella Kyriakides began her speech to the European Parliament's cancer committee by opening up with her own experience with the disease 24 years ago. She reflected on how attitudes had changed since then, when speaking about the disease was a taboo, and pointed to

“great progress”. The pandemic, Kyriakides said, had only helped reveal the fragility of health systems. “COVID-19 has proved that Europe needs to be better and needs to do more together,” she said. “Fragmentation is not the way forward.” The cancer plan, she added, is on track to be presented by the end of the year. Europe’s Beating Cancer Plan aims to reduce the cancer burden for patients, their families and health systems. It will address cancer related inequalities between and within member states with actions to support, co-ordinate and complement member states’ efforts.

## EAPM role in the battle



EAPM is aiming to rally its efforts during the next month concerning the fight against cancer – as part of its aims highlighted during the 12 October German EU Presidency Conference, ‘Ensuring access to innovation and data-rich biomarker space to speed better quality of care for citizens’, Christine Chomienne, vice-chairwoman of the EU’s Mission Board for Cancer, and professor of cellular biology at the Université Paris Diderot, and in her role as a key figure in the EU’s evolving Cancer Mission, said: “We need to change the frame of mind on cancer culture, for prevention, for policymakers, for reimbursement - but always with very strong evidence.” Outlining the development of the Cancer Mission since it started back in 2018, she underlined its determination to involve citizens and stakeholders in setting research priorities, and to develop actions geared to ensuring equal access for everyone in Europe to the best of European innovation and research resources and global know how. But to effect change, to motivate policymakers, it is also vital to communicate, she said.

**(A further update on the conference is below)**

## And goals on breast cancer

Renew Europe MEP Véronique Trillet-Lenoir, speaking at a committee meeting, pointed to breast cancer as a “model indicator” to assess the future progress of the cancer plan. There were a number of clear goals that this plan should pursue, the MEP said, from cross-disciplinary collaboration on breast cancer research, to ensuring the implementation of free mammography programs. Trillet-Lenoir explained: “Patients who had lived with the disease must have their employment and reproductive rights adequately safe-guarded.”

## 1 Million Genome

EAPM’s meeting on 21 October was very successful, with more than 220 participants, and one of the core aims of the 1 Million Genome Stakeholder Coordination Framework initiative is to support the connection of national genomics and data infrastructures, co-ordinate the harmonization of the ethical and legal framework for sharing data of high privacy sensitivity, and give practical guidance for the pan-European co-ordination of implementing genomic technologies in national and European healthcare systems. Now, at the start of the 2020s, wide-ranging changes are underway in European society and governance, with a new European Commission, a freshly elected European Parliament, and a growing conviction among Europe’s policymakers that people must be at the centre of any successful and sustainable strategy. The ambition of new Commission President Ursula von der Leyen is a Europe that “must lead the transition to a healthy planet and a new digital world”. Health Commissioner Stella Kyriakides acknowledged: “European citizens expect the peace of mind that comes with access to health care... and protection against epidemics and diseases.”

This discussion of personalised health care depicts a Europe where many chances for improvement are not yet fully being taken up. But this is not merely a catalogue of deficiencies. The variations and inefficiencies it presents are an argument for triggering radical rethinking, and for making the most of personalised healthcare. It highlights the endorsement of incentives, innovation, and investment by a new breed of

## Commission health proposals



According to a recent College of Commission agenda, the Commission is scheduled to present four different health plans on 24 November. Two of these are proposals to extend the mandate of both the European Centre for Disease Prevention and Control (ECDC) and European Medicines Agency (EMA). The third is on “preparedness and resilience in health emergency situations”, the document said. The last is the Commission’s pharmaceutical strategy, which was already planned for the fourth quarter. The Commission also scheduled the release of the Europe’s Beating Cancer Plan for 9 December. Commission Vice President Margaritis Schinas is scheduled to present all five health files.

## EU calls for action on coronavirus

European Commission President Ursula von der Leyen is hosting a press conference alongside her coronavirus adviser Peter Piot, which follows European Council President Charles Michel issuing a strongly-worded statement on Tuesday evening (27 October) on the grim situation across the EU. “Within the space of just a few weeks, the situation has escalated from worrying to alarming. Now we must avoid a tragedy,” he said. Michel praised the efforts of authorities, researchers, drug makers and the EU for their quick responses. But he lamented that efforts were not enough to prevent the resurgence of the virus. He issued a call for “determined” EU action based on two pillars: “Testing and contact tracing, and vaccines.” Michel said that PCR testing was “cumbersome to administer and to process” and needs to be supplemented with faster antigen tests, even though they’re less accurate. He also urged the EU to agree on interoperability of secure and effective applications that also guarantee privacy for an effective contact tracing system — and its countries should reach consensus on common rules for self-isolation and quarantine, he said. As far as vaccines were concerned, he said: “Our strategy and our efforts must go beyond the development and marketing of vaccines. We must avoid chaos at all costs; we must define criteria for distributing vaccines among the various countries of Europe.”

## WHO chief says COVID-19 vaccine could be ready by year-end

A COVID-19 vaccine may be ready by year-end, Tedros Adhanom Ghebreyesus, head of the World Health Organization (WHO) said on Tuesday (6 October). Ghebreyesus added: “We will need vaccines and there is hope that by the end of this year we may have a vaccine. There is hope.” He was addressing the end of a two-day meeting of its Executive Board on the pandemic. Nine experimental vaccines are in the pipeline of the WHO-led COVAX global vaccine facility that aims to distribute 2 billion doses by the end of 2021.

## Latest cases reported by the ECDC

Spain — 52,188 (including weekend stats)

France — 26,771

UK — 20,890

Italy — 17,007

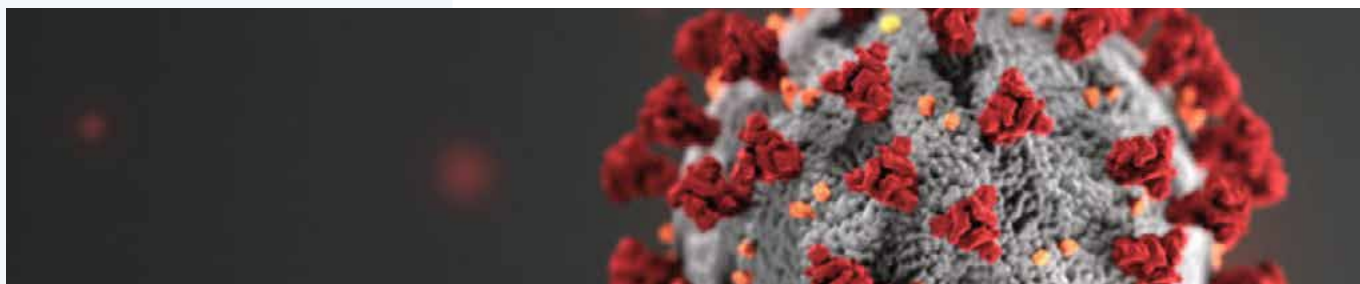
Germany — 11,409

## Trust and governance

Despite member state competence in many areas, there is undoubtedly a need for common European health legislation as much as possible, but it must be the right legislation. Unfortunately, experience has shown that having separate rules in every member state does not really work, for a variety of reasons. For example, it often leads to an R&D environment that is not competitive, slows the innovative dynamic and ultimately represents a barrier to the emergence of effective therapies for untreated disease. With more integration, collaboration, dialogue and increased trust among each and every one in the field, stakeholders can help mould the right frameworks, in the right place, at the right time. In Europe, the interdependence of member states makes it both necessary and desirable that much of that task of oversight is organized at EU level. It is, inevitably, of course, a more complex compact nowadays. Each component of the systems on which people now routinely depend for their health has to fulfil its part of the bargain.

These issues of trust will be discussed in EAPM's two presidency conferences being planned for January and July 2021 that will address governance.

## Europe needs 'serious acceleration' in fight against coronavirus: WHO



Europe needs a “serious acceleration” in the fight against the coronavirus and a lack of contact-tracing capacity could drive the disease into the darkness, a top World Health Organization official said on Monday (26 October). In Europe the picture is unrelentingly grim as a string of countries reported record increases, led by France, which posted more than 50,000 daily cases for the first time on Sunday, while the continent passed the threshold of 250,000 deaths. The 46 countries at World Health Organization level accounted for 46% of global cases and nearly one third of deaths, said Mike Ryan, the WHO's top emergencies expert. “Right now we are well behind this virus in Europe, so getting ahead of it is going to take some serious acceleration in what we do,” Ryan told a news conference.

## Council welcomes prospect of European health data space

The European Council has welcomed the European strategy for data, which supports the EU's global digital ambitions to build a true European competitive data economy. The European Council welcomes the creation of common European data spaces in strategic sectors, and in particular invites the Commission to give priority to the health data space, which should be set up by the end of 2021, and which is being cited as a means to strengthen the immediate response to COVID-19.

And it is not just the Commission that's working on digital health, with the World Health Organization also presents its global strategy for digital health, which is set to be brought to the World Health Assembly in November. The WHO is currently putting together an investment case to

implement this strategy, with member state approval being awaited, the WHO's Chief Information Officer Bernardo Mariano Jr has said. But public trust is again a big consideration, with critics asking whether people will be willing to share their data on a pan-EU platform, and whether governance will be required to ensure full participation.

### EU looks forward with health policies

DG SANTE plans to develop a new chapter for health in Europe, one that is well-equipped to deal with the ongoing COVID-19 crisis and its aftermath. EU Health and Food Safety Commissioner Stella Kyriakides stated earlier this year that “sustainability, digital transformation, and reinforced resilience will be our compasses to move forward”. DG SANTE is particularly keen to develop the ability to deliver universally accessible and affordable food, medicines, and health care long-term, despite any crisis or hurdles that Europe may encounter. One initiative able to strengthen these areas comes in the form of the new EU Health Programme, EU4Health. EU4Health is a stand-alone programme with a significantly increased budget of €9.4 billion – 23 times larger than it was at the beginning of 2020. “COVID-19 has taught us that Europe needs to give a higher priority to health, to enable it to respond better to epidemics and other unforeseen health threats,” added Commissioner Kyriakides. The programme is investing in three key areas: preparedness and prevention, available and affordable medicines, and lastly, building stronger health systems using digital tools. This programme is not only responding to the lessons learned through the rise of COVID-19, (which has indeed undoubtedly altered EU Health priorities), but also will help Europe to implement other health strategies moving forward, such as the EU's Cancer Plan and the Pharmaceutical Strategy.

### German EU Presidency Conference



Held during the auspices of the Germany Presidency of the Council of Ministers on 12 October, EAPM's conference was very successful in its own right, with an agenda packed with insights from distinguished speaker. The programme delivered a message on the immediate need for a new way of thinking about health care. It presented this urgency through discussions on adequate health care frameworks, better allocation of resources, the potential of advanced testing, co-ordinated approaches to cancers and of the deployment of advanced therapy medicinal products - all against the background of the ongo-ing battle against COVID.

More than 200 delegates attended, and there were contributions from European politicians, officials from the European Commission and the European Medicine Agency, and a multitude of key stakeholders from countries including Germany, which is presently hosting the EU Presidency. The conference brought 2020 to a fitting conclusion – almost.

### Principal recommendations

Although there was no formal process of agreeing recommendations at the meeting, the following are among the recurring elements from the discussions.

- Inequalities in access to testing and treatment across Europe must be addressed.
- Adequate data infrastructure and processing capacity must be available.

- Real-world evidence must be developed and acceptance criteria agreed with regulators, HTA agencies and payers.
- Greater flexibility in regulatory requirements is needed to accommodate evaluation of products destined for small populations.
- Multi-stakeholder collaboration must be developed to agree research priorities, standards and quality assurance of testing, and evaluation criteria for testing and treatments.
- Trust must be developed among citizens about the security and possible use of their data.
- Communication must be developed by healthcare stakeholders to persuade policymakers to effect constructive change.

The [conference report is available here](#).

### Intensive care units ‘could be overrun in weeks’ warns WHO

The World Health Organization has warned that intensive care units in Europe could be overwhelmed in a matter of weeks and that immediate action was essential to prevent essential health systems collapsing and schools closing. “In many cities around Europe, the capacity for ICU is going to be reached in the coming weeks,” said Maria Van Kerkhove, the WHO’s technical lead for COVID-19. WHO Director General Tedros Adhanom Ghebreyesus warned that the entire world, and particularly the northern hemisphere, was at a “critical juncture”.

### Coronavirus second wave brings EU summit



European Union leaders are holding a video conference next week to discuss how to better cooperate against the COVID-19 pandemic as infections rise, European Council President Charles Michel said on Wednesday (21 October). The video summit, to be held on 29 October, will be the first of a series of regular discussions that EU leaders have committed to hold to tackle the pandemic at a time when most of the member countries report alarming figures confirming a second wave. “We need to strengthen our collective effort to fight COVID-19,” Michel said on Twitter. The discussion, due to start in the late afternoon, will take place a day after the Commission is expected to announce new plans to strengthen coordination among EU states on testing strategies, contact tracing and quarantine length, officials told Reuters. The EU’s 27 nations fought COVID-19 with different, sometimes contrasting measures, in the first months of the pandemic. The tighter co-ordination is expected to prevent a repeat of the divisions seen after the first wave.

### Coronavirus: EU interoperability gateway goes live

To exploit the full potential of contact tracing and warning apps to break the chain of coronavirus infections across borders and save lives, the Commission, at the invitation by member states, has set up an EU-wide system to ensure interoperability – a so-called ‘gateway’. After a successful pilot phase, the system goes live today with the first wave of national apps now linked through this service: Germany’s Corona-Warn-App, Ireland’s COVID tracker, and Italy’s immuni. Together, these apps have been downloaded by around 30 million people, which corresponds to two-thirds of all app downloads in the EU. Single Market Commissioner Thierry Breton said: “Many Member States have launched voluntary contact tracing and warning apps, and the Commission has supported them in make these apps safely interact with each other. Free movement is an integral part of the Single Market – the gateway is facilitating this while helping save lives.”

## ENVI adopts all EU4Health compromise amendments



The European Parliament's health committee has passed all compromise amendments for the EU4Health programme. The amendments establish that the Parliament will receive €9.4 billion – which was the budget originally proposed by the Commission – for the programme, after the Council reduced this to €1.7 billion during budget talks in summer. The health committee's report sets the Parliament and Commission on the same side of negotiations against the Council. The vote, planned for Monday (12 October), was delayed until this morning due to technical difficulties.

### European health union plans to be unveiled on 11 November

The Commission will propose its new plans for a European health union on November 11, according to a new College of Commissioners agenda. The agenda shows four proposals scheduled for 11 November, including a plan for “building a European health union: preparedness and resilience”, proposing a regulation on handling serious cross-border health threats and mandate changes for the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC). The Commission's pharmaceutical strategy is nevertheless scheduled for 24 November, and Europe's Beating Cancer Plan for 9 December.

### WHO head criticizes herd immunity approach

The head of the World Health Organization has ruled out a herd immunity response to the pandemic. Herd immunity occurs when a large portion of a community becomes immune to a disease through vaccinations or through the mass spread of a disease. Some have argued that coronavirus should be allowed to spread naturally in the absence of a vaccine. But WHO chief Tedros Ghebreyesus said such an approach was “scientifically and ethically problematic”. Speaking at a news conference on Monday, Dr Tedros argued that the long-term impacts of coronavirus - as well as the strength and duration any immune response - remained unknown. “Herd immunity is achieved by protecting people from a virus, not by exposing them to it,” he said.

### EU4Health programme - Parliament pushes for €9.4 billion

The European Parliament wants to restore the €9.4 billion originally planned for the EU's health program in the EU budget. As Environment, Public Health and Food Safety Committee (ENVI) members vote on the EU4Health Programme, the European Public Health Alliance (EPHA) has prepared a number of voting recommendations for them to consider, as they finalize their position. To ensure a strong public health programme, the EPHA proposals are based on the following principles:

1. Include the commercial determinants of health and one health concept in the Programme;
2. Guarantee disease prevention and health promotion;
3. Promote evidence, right based and multisectoral responses to communicable diseases;
4. Develop a European strategic framework to tackle non communicable diseases and support national actions;
5. Ensure affordable access to quality medicinal products, care and prevention services;
6. Implement the Health in All Policies approach by compulsory health impact assessments;

7. Tackle the cross-cutting health aspects and connections with other Commission policies including the EU Green Deal and Horizon Europe;
8. Address soaring health inequalities;
9. Ensure meaningful involvement of public interest NGOs to implement the policies.

## Political regeneration on COVID-19?



The great writer George Orwell, in his 1945 essay *Politics and the English Language*, wrote that “to think clearly is a necessary first step towards political regeneration”. And so, therefore, where exactly do we stand as far as ‘clear thinking’ is concerned on COVID-19? There can be no doubt that the pandemic has placed research and higher education sectors squarely before the public attention. The capacity of all laboratories has been absolutely vital as far as diagnostic testing is concerned, while those in the know on infectious diseases, epidemiology, public health, mathematical modelling, and economics have taken a large portion of national policy making and media coverage. There can be no doubt that the collective global future is heavily dependent on an effective vaccine being developed, as quickly as possible, against severe acute respiratory syndrome coronavirus 2.

**And that is all for now, stay safe and well. EAPM will return soon with our regular update.**

### In the news

#### **Why increasing trust between stakeholders must be way forward for health**

<https://www.eureporter.co/frontpage/2020/10/27/eapm-why-increasing-trust-between-stakeholders-must-be-way-forward-for-health/>

#### **Success for 1 Million Genome Stakeholder Coordination Framework meeting, Health Union takes shape, second wave hits Italy and Germany**

<https://www.eureporter.co/frontpage/2020/10/22/success-for-1-million-genome-stakeholder-co-ordination-framework-meeting-health-union-takes-shape-second-wave-hits-italy-and-germany/>

#### **Last chance to register for Million Genome Stakeholder Coordination Framework meeting and a ‘stronger’ European Health Union is on the horizon**

<https://www.eureporter.co/frontpage/2020/10/20/eapm-last-chance-to-register-for-million-genome-stakeholder-co-ordination-framework-meeting-and-a-stronger-european-health-union-is-on-the-horizon/>

#### **Update: Co-operation under the microscope in COVID-19 crisis – EAPM EU Presidency Conference report available**

<https://www.eureporter.co/health/2020/10/20/update-co-operation-under-the-microscope-in-covid-19-crisis-eapm-eu-presidency-conference-report-available/>

#### **Update: EAPM B1MG meeting to bring together national genomics and data infrastructures online for 21 October**

<https://www.eureporter.co/frontpage/2020/10/16/update-b1mg-meeting-to-bring-together-national-genomics-and-data-infrastructures-online-for-21-october/>



**EAPM enjoys great success with virtual German EU Presidency conference, ENVI adopts EU4Health amendments, EU Beyond 1 Million Genomes Event on 21 October**

<https://www.eureporter.co/frontpage/2020/10/13/eapm-enjoys-great-success-with-virtual-german-eu-presidency-conference-envi-adopts-eu4health-amendments-eu-beyond-1-million-genomes-event-on-21-october/>

**Presidency conference building consensus for progress on innovative personalised medicine in a COVID 19 and post-COVID 19 world**

<https://www.eureporter.co/health/2020/10/12/presidency-conference-building-consensus-for-progress-on-innovative-personalised-medicine-in-a-covid-19-and-post-covid-19-world/>

**Last chance to register for EU Presidency Conference and tackling polarization of opinion through consensus building**

<https://www.eureporter.co/health/2020/10/09/eapm-last-chance-to-register-for-eu-presidency-conference-and-tackling-polarization-of-opinion-through-consensus-building/>

**Thinking clearly on COVID-19, all ready for the EU Presidency Conference on 12 October: Register now!**

<https://www.eureporter.co/health/2020/10/09/eapm-last-chance-to-register-for-eu-presidency-conference-and-tackling-polarization-of-opinion-through-consensus-building/>

**EU Presidency conference ahoy, and spare a thought for the carers**

<https://www.eureporter.co/health/2020/10/05/eapm-eu-presidency-conference-ahoy-and-spare-a-thought-for-the-carers/>

**Newsletter arrives, conference en route, Commission to present health proposals**

<https://www.eureporter.co/health/2020/10/02/eapm-newsletter-arrives-conference-en-route-commission-to-present-health-proposals/>