



European Alliance for Personalised Medicine

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Next EAPM events

18 September, 2020:

ESMO High Level Roundtable 'Seeking innovation solutions at for cancer patients and citizens'

13-14 October, 2020:

German Presidency Conference: "Building a decentralised, data-rich biomarker space to speed better care and quality of life for citizens and patients"

November 2020:

2nd EAPM Global Conference: "Providing a global forum to ensure Public Trust in empowering Digital Data for health Science in a Covid and Post Covid World"

Latest lockdown measures put many holidays at risk - EAPM resolves to continue battle against pandemic

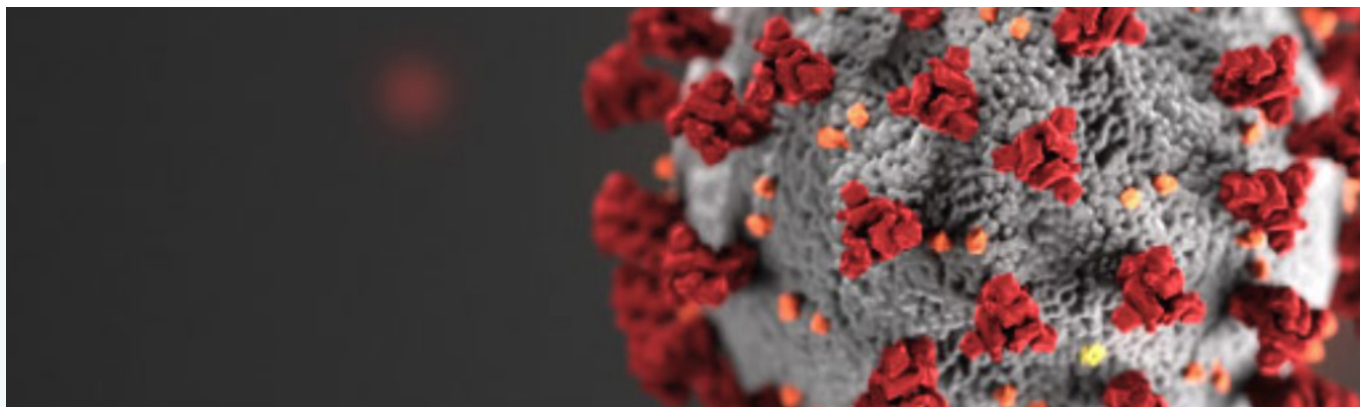
Hello, and welcome to the European Alliance for Personalised Medicine (EAPM) newsletter for August. We hope that, despite the latest quarantine restrictions that have been put in place in the UK as of 25 July, which mean that all returning UK visitors from certain areas of Spain will have to self-isolate for 14 days following their return to Blighty, and with concerns that similar measures may be once again put in place for Germany, France and Belgium, all our correspondents manage to find some time, and place, to relax over the weeks ahead. Here's hoping...more about the renewed measures later in the newsletter.

Before we get into the latest news-bulletin items, just a quick word about how successful EAPM's Global Conference on 14 July was. In our first Global Conference of its kind, more than 480 delegates attended worldwide, with countries from all over the world, including China, Japan, Australia, New Zealand, Malaysia, Brazil, Peru, Cuba, Rwanda, South Africa and, of course, North America, and the EU represented. The conference brought together representatives of distinct disciplines and interests - public health decision makers, regional institutions, politicians, patient organizations, and associations engaged in personalised health care, and the principal subject for discussion explored the connections and parallels between tackling COVID-19 and developing personalised medicine. With EAPM's continual promotion, during the COVID-19 pandemic, of personalised medicine into global health-care systems, the conference concluded that such an approach allowed the health of all citizens to benefit from the uptake of innovative medical interventions tailored to the specific needs of individual patients, providing better treatment, preventing undesirable adverse reactions, and fostering a more efficient and cost-effective health-care system. EAPM looks forward to the next event of this kind. You can find the report of the Global conference [available here](#).

And, as far as upcoming EAPM events are concerned, on 18 September, there will be an ESMO High Level Roundtable 'Seeking innovation solutions for cancer patients and citizens', [click here to register](#) and [here](#) for the agenda, and on 13-14 October, the German Presidency Conference, 'Building a decentralised, data-rich biomarker space to speed better care and quality of life for citizens and patients' and registration will open here towards the end of August.

And now, on with the news...

Coronavirus resurgence in Germany brings deep concern for health authority



Germany's public health authority has described the country's recent increase in coronavirus cases as a reason for concern. Lothar Wieler, the president of the Robert Koch Institute (RKI) for disease control, said he was "very worried by the new developments," adding that there could be signs of a second wave. Over the past seven days, Germany registered 3,611 new cases. Germany announced on Monday (27 July) a programme of free, mandatory coronavirus testing for travellers returning from a list of high-risk countries. The list currently includes Brazil, Turkey and the US, and officials said it will be updated daily. Wieler has now asked people for the first time to wear a mask outdoors if they cannot maintain a physical distance of at least 1.5 metres (5ft). Previously the guidance had been to wear masks indoors in public. The head of the RKI said Germans must stop the virus once again spreading "rapidly and uncontrollably" by following hygiene and distancing measures. "We don't know yet if this is the beginning of a second wave but of course it could be," Wieler said. "But I am optimistic that if we follow the hygiene rules we can prevent it, it's up to us." In addition, Germany's health minister has announced plans to make tests mandatory for people returning from at-risk areas. The initial plan was to provide the tests free, but on a voluntary basis.

Belgium increases social restrictions amid coronavirus spike

Belgium has announced a tightening of social restrictions to contain the spread of coronavirus after a spike in infections. Sophie Wilmes, the Belgian prime minister, said that from Wednesday a family or those living together can meet only the same five people from outside their household over the next four weeks. This marks a drop from the 15 different people an individual is currently allowed to meet per week. Under the new rules, the so-called "social bubble" applies to a house and its occupants and not to individuals. "Our aim is clear - avoid another full lockdown," Wilmes said.

Orphan drug regulations – ‘patient-centricity’ problems cited



An external study for the Commission’s review of orphan drug regulations highlights numerous shortcomings and unintended consequences, and new guidance is needed to address the underrepresentation of patient-reported outcomes (PROs) in rare disease research, and the Orphanet Journal of Rare Disease has published a review of the study.

“Not only are PROs rarely used as high-level endpoints in clinical trials or taken into account in labeling claims, they are also under-researched overall—there are too few measures for the multitude of rare diseases,” wrote the authors.

Currently, there are an estimated 6,000 to 8,000 identified rare diseases worldwide, with another estimated 250 to 280 new ones being discovered each year.

The review revealed that despite an increase in interest surrounding the use of PRO measures (PROMs) in rare disease trials over the past 15 years, the trend appears to be too slow to keep up with the rise in rare diseases that are discovered per year. Additionally, the authors noted that none of the current initiatives describing methods for developing PROMs in rare diseases provide clear guidance for clinical researchers.

Using data collected from the European Medicines Agency (EMA) and FDA websites and the US government website for clinical trial information, researchers were able to compile a total of 109 rare disease articles addressing 81 therapeutic indications where only 34 rare disease specific PROMs were found.

Authors said that the data they collected demonstrated “that there remains a gap between the importance given to these constituencies and the extent of patient-centricity in orphan drug development.”

And EAPM has also had an important multistakeholder authorship academic article published on the same subject – the title is: Time for change? The why, what and how of promoting innovation to tackle rare diseases – Is it time to update the EU’s Orphan Regulation? And if so, what should be changed?

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

Increased cancer deaths due to coronavirus delays



Since a national lockdown was introduced across the UK in March, in response to the COVID-19 pandemic, cancer screening has been suspended, routine diagnostic work deferred, and only urgent symptomatic cases prioritised for diagnostic intervention. In this study, we estimated the impact of delays in diagnosis on cancer survival outcomes in four major tumour types. Substantial increases in the number of avoidable cancer deaths in England are to be expected as a result of diagnostic delays due to the COVID-19 pandemic in the UK. Urgent policy interventions are necessary, particularly the need to manage the backlog within routine diagnostic services to mitigate the expected impact of the COVID-19 pandemic on patients with cancer. EAPM will be working closely with MEPs and UK MPs in the coming months to attempt to reduce the problem.

German EU Presidency

We've suggested before that German Health Minister Jens Spahn backs giving the EU more health power, to a degree. And now that Germany has taken over the rotating presidency, we should hear more about that. Actually, we already have. Spahn, according to Politico, said there's added value in letting Brussels play a bigger role on health. He gave examples including patient mobility in transmittable diseases and reference networks for patients with cancer or rare diseases. He insisted, however, that health systems are a Member State competence, not least because they are "linked with the culture of a country, plus tradition plus history". "When it comes to coverage, when it comes to financing...that should remain on a national level," he said, while using similar arguments on HTA and the mandatory aspects of the Commission's plans. On HTA Spahn said: "In general, we are so supportive...if you have the same scientific framework, there should not be a different result in Riga, Rome, Amsterdam or Madrid."

UK plans 'biggest flu vaccination programme in history'

While hundreds of thousands of people nationwide in the UK have been understandably concerned about a far more serious ailment in recent months, namely coronavirus, there is at least some good news with the government's announcement that millions more people in the UK will be offered a free flu vaccine later this year in an effort to reduce pressure on the National Health Service (NHS) ahead of a possible second peak of the coronavirus in winter.

The Conservative government has announced its plans to vaccinate some 30 million people against the flu, in what is being described as the most comprehensive flu programme in the country's history.

Free flu vaccination will be extended for the first time to people aged between 50 and 64, the government said. At-risk groups that will also get the vaccine for free are children who are up to 11 years old; people over 65; and pregnant women.

People who are currently on the government’s list as “shielding” from the coronavirus, as well as the members of their household, will also be offered a free vaccination.

“This will be the biggest flu vaccination program in history, and will help protect our NHS as we head into winter,” said Health Secretary **Matt Hancock**.

Spanish fly from lockdown easing



With global cases of coronavirus rising by one million in the past four days, and a sharp spike being reported in Spain and other European countries, the UK government has said it had to act “rapidly and decisively” to impose a 14-day quarantine on people arriving in the UK from Spain, a minister has said. Health minister Helen Whately told the BBC it was the “right thing to do” as the UK’s virus rate must be kept “right down” to avoid a second spike. She added that No 10 would keep the quarantine policy for other countries under review.

Labour has called for financial support for people having to quarantine. The party says there is no guarantee employers will allow people to work from home for two weeks. Whately said that after all the “sacrifices” made during the lockdown, and now that restrictions are being “cautiously” and “carefully” reduced, the UK cannot take the risk of going back to a situation of rising virus rates across the country.

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Recovery efforts: Focus on quantum computing and immunotherapy

Despite the increase in France of reported cases of coronavirus, Paris has said it will put an emphasis on quantum computing and immunotherapy as part of its recovery efforts, France’s Economy Minister Bruno Le Maire said.

“Our challenge is to find the right balance between immediate action and long-term investment,” the minister told French newspaper *Le Figaro*.

And the European Commission has offered its support in the field of high-performance computing (HPC) in order to help find a treatment for the novel coronavirus.

Three powerful European supercomputing centres – located in Bologna, Barcelona and Jülich – are currently participating in the Exscalate4CoV project, along with a pharmaceutical company and several large biological and biochemical institutes. The project was launched after the Commission’s emergency call for expression of interest on 31 January 2020, receiving €3 million worth of funding for research on COVID-19 vaccine development, treatment and diagnostics. The project is part of the coordinated EU response, which aims to work on a concrete platform for finding a drug to be used against coronavirus.

This EU funding has boosted the work done with supercomputers to research drug therapy against COVID-19, by complementing the classical trial and error clinical approach and possible experimentation in patients. This is achieved by comparing the protein of the coronavirus against molecules that are stored in current databases. Excalate4CoV is currently processing digital models of the coronavirus’ protein and matching them against a database of thousands of existing drugs, aiming to discover which combinations of active molecules could react to the virus.

A broader effort in the field of HPC is also taking place, with one example being the **Partnership for Advanced Computing in Europe (PRACE)**, which aims to provide researchers with access to supercomputing resources and contributing to their coronavirus-related activities.

“Long-term investment will be in new technologies,” Le Maire added, as he identified three core areas: digital, health and sustainability.

Kostadin Angelov named Bulgarian health minister

The Coalition for Epidemic Preparedness Innovations (CEPI), a global partnership created in 2017 to develop vaccines to prevent future epidemics, has launched a call to support the rapid development and global manufacture of COVID-19 vaccines. The EU will co-fund the call with €100 million.

The EU support is part of the pledge to invest €1 billion from Horizon 2020, the EU research and innovation programme, into urgently needed research and innovation to test, treat and prevent COVID-19. Half of this funding – 50 million – had been already planned under the partnership between the Commission and CEPI. The amount was doubled after the coronavirus outbreak.

Innovation, Research, Culture, Education and Youth Commissioner Mariya Gabriel said: “We need efficient treatments and vaccines to eliminate the danger of the coronavirus. That is why we are proud to support CEPI in its endeavour to rapidly develop the most promising vaccine candidates.”

In response to the coronavirus pandemic, CEPI is working to rapidly develop a broad portfolio of the most advanced COVID-19 vaccine candidates and to ensure that these are ready to be produced at scale, in collaboration with industry partners. Through COVAX, the vaccines pillar of the ACT Accelerator launched in partnership with Gavi and the World Health Organization (WHO), CEPI’s ultimate goal is to provide an end-to-end solution to develop, manufacture and equitably deliver up to two billion doses of vaccine by the end of 2021.

The Horizon 2020 support to CEPI will fund research and innovation activities but not manufacturing of vaccines. The new call is an extension of CEPI’s second COVID-19 vaccine call for proposals launched in May. It is open until the end of September but proposals will be evaluated every three weeks in order to secure research funding in a timely manner. As part of the Coronavirus Global Response initiative led by President Ursula von den Leyen, €15.9 billion has been pledged for universal access to tests, treatments and vaccines against coronavirus and for the global recovery.

COVID-19: 10 things the EU is doing to ensure economic recovery

1. Providing massive economic stimulus

To help Europe recover from the devastating economic repercussions wrought by the coronavirus pandemic, the European Commission has proposed a €750 billion stimulus plan, coupled with a revised proposal for the EU’s next long-term budget (2021-2027). The plan - known as Next Generation EU - sees the Commission borrowing money on financial markets, using its high credit rating to secure low borrowing costs. The Parliament insists that the Green Deal is at the heart of the recovery package and wants to avoid burdening future generations. EU leaders reached a deal on the budget and recovery plan mid-July. Though MEPs welcomed the agreement on the recovery package, they regretted the decrease in grants. Parliament said the agreement on the long-term budget put EU priorities such as the Green Deal and the Digital Agenda at risk and said it was prepared to withhold its consent unless the deal is improved.

2. Supporting EU health systems and infrastructures

With several experts mentioning the possibility of a second wave or future pandemics, buttressing the EU’s response capacity to health crises is key. To help Europe cope with future outbreaks, the EU launched the new EU4Health programme, which will bolster member states’ healthcare systems as well as fostering innovation and investment in the sector. EU4Health is part of the Next Generation EU recovery plan. The Parliament had insisted on the creation of a new stand-alone European health programme.

3. Protecting small and medium-sized businesses

Small and medium-sized enterprises represent 99% of all businesses in the EU, making their survival crucial to the EU's economic recovery. The EU unlocked €1 billion from its European Fund for Strategic Investments to incentivise banks and lenders to provide liquidity to more than 100,000 European small businesses.

4. Mitigating unemployment risks

Jobs have been hard hit by the pandemic, with unemployment figures rising dramatically. To help workers in the wake of the Covid-19 crisis, the EU's Support mitigating Unemployment Risks in Emergency (Sure) initiative will provide financial assistance of up to €100 billion to member states in the form of loans granted on favourable terms to help cover the costs of national short-time work schemes.

5. Supporting the tourism industry

Another sector badly affected by the pandemic is tourism. Europe is the world's number one tourist destination and the EU introduced a series of measures designed to help the industry cope during the crisis, as well as a package to reboot Europe's tourism in 2020 and beyond. Relief measures for the transport sector were also introduced, to minimise the effects of the pandemic on airlines, railways, road and shipping companies. To help people travel in Europe as various countries gradually lift lockdown measures, the Re-open EU interactive tool provides travellers with the information they need to confidently plan their travel and holidays in the EU while staying healthy.

6. Banking package to support households and businesses

To ensure banks continue providing loans to businesses and households to mitigate the economic fallout from the crisis, the Parliament approved a temporary relaxation of prudential rules for European banks. Changes to the capital requirements regulation will enable pensioners or employees with a permanent contract to get loans under more favourable conditions, ensure credit flows to small and medium-sized enterprises and support infrastructure investment.

7. Supporting agriculture and fisheries

In order to avoid disruption to food supplies and prevent food shortages, the Parliament approved emergency measures to help farmers and fishermen affected by the Covid-19 pandemic. Measures include supporting fishermen and aquafarmers who have had to stop their activity during the crisis and an increasing the support EU countries can give to small firms dealing with farm food. Exceptional market measures were also introduced to support EU wine, fruit and vegetable producers.

8. Helping countries fund their crisis response

To help member states fund their coronavirus crisis response, the EU launched a new initiative, the Coronavirus Response Investment Initiative. It will channel some €37 billion from EU structural funds to provide immediate financial support to EU countries trying to help people and regions face the current crisis.

9. Relaxing state aid rules

As the pandemic was beginning to spread throughout Europe, the EU launched a Temporary Framework on state aid rules to ensure sufficient liquidity remains available to businesses of all types

and help maintain economic activity during and after the COVID-19 outbreak. Member states will be able to grant up to €800,000 to a company to address urgent liquidity needs or grant loans with favourable interest rates.

10. Protecting weakened European businesses from foreign competitors

The economic impact of the coronavirus pandemic has left many European companies vulnerable to subsidised foreign competitors. To help protect businesses, the Parliament called for a level-playing field for all businesses, to avoid distortions to the single market stemming from unfair competition from foreign companies. The Commission also launched a public consultation on how to deal with the negative effects caused by foreign subsidies. In parallel, the EU issued guidelines for member states on foreign direct investment, urging them to thoroughly screen investments from outside the EU to avoid risks to the EU's

And, finally...a little good news

Human trials of Russia's second potential coronavirus vaccine, developed by the Siberian Vector institute, began on 27 July, the TASS news agency cited Russia's consumer safety watchdog as saying on 24 July. An early-stage human trial of a separate vaccine, developed by the Gamaleya institute in Moscow, was completed this month, with scientists hailing the results and authorities planning to move to mass production in the autumn.

And that's all for now - as best as you can, enjoy your August break, stay safe and well, and see you in September!

Links

- [Mark your card for upcoming Alliance events for ESMO Congress in September and Presidency Conference for October](#)
- [Time for change concerning rare diseases](#)
- [From Global Conference to Captain Sir Tom Moore](#)
- [EAPM Global Conference - Getting in stride for cautious summer](#)
- [Update: Global Conference heads up hectic week for EAPM](#)
- [Cancer risks in COVID, matters of the heart, EU4Health funding](#)
- [EAPM goes global - join us on 14 July](#)
- [#EAPM looks to the rentrée with hope and resolution for public health.](#)