



European Alliance for Personalised Medicine

EAPM Bulletin: Issue 67, October 2020

euapm.eu

Next EAPM events

12 October 2020:

EAPM German Presidency Conference “Ensuring Access to Innovation and data-rich biomarker space to speed better quality of care for Citizens”

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”

Greetings, one and all, and welcome to the European Alliance for Personalised Medicine (EAPM) October newsletter. We're all looking forward to EAPM's organization of the German EU Presidency conference on 12 October - read on for news of EAPM's recent ESMO conference, the European Health Union, coronavirus rises in the UK and France, and the publications Digitalisation and COVID-19: The Perfect Storm and Bringing Greater Accuracy to Europe's Healthcare Systems: The Unexploited Potential of Biomarker Testing in Oncology.

German EU Presidency conference

EAPM is looking forward with great excitement to its organization of the upcoming German EU Presidency conference on 12 October, ‘Ensuring Access to Innovation and data-rich biomarker space to speed better quality of care for Citizens’. Given the present circumstances with COVID-19, the conference will of course be online, but it will be featuring keynote speakers from the world of health and elsewhere - EAPM's role in the conference has always proved popular in previous years, and time is ticking away - you can find the agenda [here](#), and register [here](#).

This event will be the third Presidency conference that EAPM will be holding during 2020 - during the Croatia Presidency, a bridging conference between the Croatia and Germany presidencies, and this final event while Germany is at the helm. All three events 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 European Parliament and the European Commission. And, of course, since the start of the year we have been dealing with impact and fall out of the COVID-19 crisis.

The target audience for the conference will be numbers of industry professionals, government regulators, patients, academia, and exhibitors all striving to drive insights to action, and the sessions during the conference will cover a variety of essential subject areas.

Proceedings will begin with ‘Multi-stakeholder approach - Rational Allocation of Resources to

support innovation and healthcare system efficiencies – Who to test, when to test and how to test?’ This will feature participation from Joern-Peter Halle, Head of Research, Global R&D Healthcare and Merck KGaA Benedikt Westphalen, University Hospital Munich, Department of Internal Medicine III & Comprehensive Cancer Center Munich, Germany.

‘Biomarker testing: Piercing the fog of Alzheimer’s and related dementia’ features, among others Karim Berkouk, Deputy Head of Unit for Combatting Diseases, DG Research and Innovation, European Commission, Timo Grimmer, Professor, Department of Psychiatry and Psychotherapy, Klinikum rechts der Isar der Technischen Universität München Dinko Mitrecic, Head of the Laboratory for Stem Cells, Croa-tian Institute for Brain Research, University of Zagreb School of Medicine, with Denis Horgan in the chair once more.

‘Propelling Healthcare with Advanced Therapy Medicinal Products (ATMPs) fea-tures, among others, Falk Ehmann, chair of the Innovation Task Force, EMA Oume-ya Adjali, Directrice du laboratoire, Universite de Nantes, Nantes, France Thomas Szucs, Unversity of Basel, European Center for Pharmaceutical Medicine.

Finally, the closing session will cover ‘Realising the potential of Data & Early Diag-nosis through biomarker testing & Molecular Diagnostics’, with chairman Denis Horgan bringing proceedings to a close.

European health union



The EAPM has always flagged up the need for more co-operation at EU level. The Alliance has been calling on this for years, as far back as during the early stages of the cross-border health care directive, as well as in respect of the recent (and current) HTA negotiations. European Commission President Ursula von der Leyen said her Commission would try to reinforce the European Medicines Agency and European Centre for Disease Prevention and Control. She has urged EU members to build a stronger health union, promising a biomedical research agency and a global sum-mit. In her first annual State of the European Union address, Ursula von der Leyen said the coronavirus pandemic had underlined the need for closer cooperation, stressing that people were “still suffering”.

“For me, it is crystal clear – we need to build a stronger European Health Union,” she said. “And we need to strengthen our crisis preparedness and management of cross-border health threats.” Von der Leyen said her Commission would try to rein-force the European Medicines Agency and European Centre for Disease Prevention and Control. And she announced the creation of a new agency for biomedical advan-ced research and development dubbed BARDA. She said she would work with Italy during its presidency of the G20 - a grouping of the world’s richest countries - to convene a global health summit next year to share the lessons of the coronavirus cri-sis. “This will show Europeans that our Union is there to protect all,” she said. Health policy remains the responsibility of EU member states and, while Brussels has tried to coordinate the bloc’s response to the epidemic, national lockdowns and border rules have varied widely. Von der Leyen, a doctor by training, also warned countries not to act selfishly when on vaccines, which are widely seen as the solution to end the crisis. The European Parliament plans to discuss this in the weeks to come and EAPM is engaging with them on issues as outlined [here](#).

ESMO conference



Divided into four round tables, the EAPM conference at the ESMO Congress on 18 September dealt with such diverse issues as tumour agnostics, which was the first session, biomarkers and molecular diagnostics and real-world evidence in a health-care setting. Concerning cancer, specifically tumours, the congress stated that tissue-agnostic cancer drugs are antineoplastic medicines that treat cancers based on the mutations that they display, instead of the tissue type in which they appear. These drugs include, for example, Entrectinib, Pembrolizumab and Larotrectinib.

The potential of technologies in fighting cancer is under-exploited. To highlight the barriers, EAPM organised exchanges on making more use of tumour agnostic medicines, molecular testing and diagnosis, and the wealth of real-world data that could speed new product development. The forum for these exchanges was a roundtable during ESMO, and it brought together experts from across the widest range of stakeholders – clinicians, academics, pathologists, policymakers, industry and patients.

On tumour agnostics, key recommendations were as follows:

- **Government support for regional/national patient registries for RW**
- **Search for a common approach to assessment of TAX among HTA and regulators**
- **Alignment of data across countries**

On biomarkers and molecular diagnostics, key recommendations were as follows:

- **Government support for NGS testing infrastructure**
- **Government support to achieve best standard of care for biomarker testing.**

On Real-World Evidence, key recommendations were as follows:

- **Government support for regional/national patient registries for RWD**
- **EU regulators should support the use of real world data for approval and re-imburement of new therapies at the member state level**
- **The opinions of patients with conditions for which there are currently limited treatment options must be incorporated when considering alternative evidence bases such as realworld data**

All recommendations made can be found in the ESMO report, see below.

The discussions resulted in sharper definition of the barriers and clearer understanding of distinct points of view on how to surmount them. EAPM Executive Director Denis Horgan, who moderated the roundtable, underlined the importance of bridges between the testing laboratory and lawmakers. The principal conclusion was that since good policy depends on good science, it is the responsibility of stakeholders – and particularly the scientific community and the patients it serves – to ensure that the issues are better understood by the policy community, and taken account of in policy formation.

The ESMO report is available by clicking [here](#).

This type of interaction is a key part of EAPM's stated goals – to engage with the medical community whenever possible, and at every level, particularly during these tough times of the pandemic.

Lung cancer report



EAPM's fourth ESMO 2020 round table and report on lung cancer, was entitled '**Seeking Response Not Just In Words And Plans But In Action**'. Since EAPM was created in 2009 it has been contributing actively to EU cancer policy, and of particular concern is how delays to screening, diagnosis and treatment of cancer have already impacted morbidity and mortality rates, with cancer death rates looking like-ly to rise significantly over the coming years. While devastating, these diagnostic and treatment delays are also compounding a pre-existing problem – a worrying lack of knowledge among the public of some of the least-survivable cancers and their sym-poms.

The report on lung cancer is available by clicking [here](#).

Concluding Action points for discussions in the context of the EU's Beating Cancer Plan, Cancer Mission, EU Health Data Space, the review of research incen- tives in its orphan drug rules, the Pharmaceutical Strategy, the draft EU- 4Health programme and the promised European Health Union were the following:

Towards policymakers:

- Promote investment in high quality testing (via Cancer Mission)
- Promote common approach to assessment of new technologies among HTA and regulators
- Promote support among regulators for the use of real-world data for approval and reimbursement of new therapies
- Promote support for regional/national patient registries for Real World Evidence
- Promote support for adequate laboratory and data infrastructure in Europe
- Promote interpretations of General Data Protection Regulation that permit data use for research
- Promote investment in outcomes data, with focus on patient experience.

Towards stakeholders:

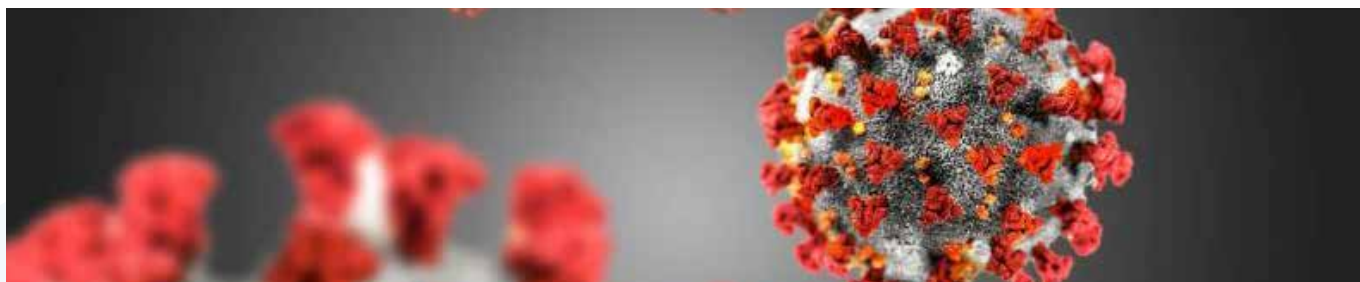
- Ensure patient opinion is incorporated into discussions of evidence bases
- Ensure continued cooperation among stakeholders on pan-cancer studies
- Ensure rapid delivery of high-quality and clear test results for therapeutic decision-making
- Collaborate in clear messaging to policymakers on areas of agreement

Academic publications in September announced

In addition, EAPM has released 'Bringing Greater Accuracy to Europe's Healthcare Systems: The Unexploited Potential of Biomarker Testing in Oncology', which can be viewed by [clicking here](#) and which provides information on what biomarkers are and what they achieve in the fight against cancer. However, Europe is missing out on major opportunities. The rapid growth in the availability of techniques – known as biomarker testing – has made it possible to improve European citizens' health. Their widespread adoption would support continued improvements in outcomes for diseases such as cancer. And the prospects are even more attractive if the development and deployment of more sophisticated biomarkers is encouraged. But these opportunities are not being grasped. For the sake of patients, and for health-care systems, it is time to do so.

In addition, EAPM has recently released an academic publication entitled **[‘Digitalization and COVID-19: The Perfect Storm’](#)**. This is also due to be discussed at our upcoming presidency conference, and the article addresses the premise of health care as a ship in the harbour which is safe, but that is not what ships are built for, as observed by the 19th century philosopher William Shedd. In other words, technology of high potential is of little value if the potential is not exploited. As the shape of 2020 is increasingly defined by the coronavirus pandemic, digitalization is like a ship loaded with technology that has a huge capacity for transforming mankind’s combat against infectious disease.

Coronavirus deaths pass 1 million



The global death toll from COVID-19 rose past 1 million on 29 September, according to a Reuters tally, a bleak milestone in a pandemic that has devastated the global economy, overloaded health systems and changed the way people live. The number of deaths from the novel coronavirus this year is now double the number of people who die annually from malaria – and the death rate has increased in recent weeks as infections surge in several countries. “Our world has reached an agonizing milestone,” UN Secretary-General Antonio Guterres said in a statement. “It’s a mind-numbing figure. Yet we must never lose sight of each and every individual life. They were fathers and mothers, wives and husbands, brothers and sisters, friends and colleagues.” And the World Health Organization has warned that there could be 2 million deaths before a vaccine is ready to use.

Vaccination percentages

The EU, Britain and other EU partners such as Switzerland and Norway want a future vaccine to cover 40% of their populations, as opposed to the 20 percent initially set out by the global procurement mechanism COVAX. According to a document adopted late July, the countries noted that at-risk groups account for around 40% of the population.

Back to school

According to a study by BMJ, COVID-19 has not caused the deaths of any otherwise healthy schoolchildren in the UK. Children’s risk of needing hospital treatment for coronavirus is “tiny” and critical care “even tinier”, they say. However, black children, those who are obese and very young babies have a slightly higher risk. The BMJ study looked at 651 children with coronavirus in hospitals in England, Wales and Scotland. It covers two-thirds of all children’s admissions in the UK due to COVID-19 between January and July and confirms what is already known about the minimal effects of the virus on children.

Health systems brace for viral overload

Doctors are anticipating that the collision of COVID-19 and cold and flu season could bring a new host of health-care challenges when the cold weather sets in. Researchers have said there are significant similarities between the symptoms of COVID-19 and those of a cold or flu, including coughing, congestion and body aches. This diagnostic overlap can make it difficult for doctors to distinguish the sniffles from the deadly disease, and the only way to know for sure is through testing. As school resumes, scientists say it’s unclear whether classes should be closed. Health agencies are helping hospitals prepare for an influx of patients with the flu and other respiratory illness, which could burden emergency rooms, acute-care units and the availability of beds. And the World Health Organization

(WHO) states that 90% of countries from five regions have seen their health systems disrupted due to coronavirus.

Scientists look to plasma treatment



Since early in the pandemic, scientists have said antibodies that the immune system makes to fight the coronavirus could be crucial in finding a cure for COVID-19. In the US, the Food and Drugs Administration (FDA) recently authorized one of these treatments – convalescent plasma, in which the antibody-rich portion of blood do-nated by recovered COVID-19 patients is given to people hospitalized with the dis-ease. But the study, which is available as a non-peer-reviewed preprint, wasn't place-bo-controlled, and results from rigorous clinical trials with COVID-19 convalescent plasma have yet to be published.

Backlash against US refusal to join vaccine efforts

The Wellcome trust has warned the US over its inability to “bounce back” in re-sponse to the news that the country will not be joining COVAX. Head of Global Pol-icy Alex Harris said that the pandemic will only end if “countries work together”. The EU wants to vaccinate at least 40% of its population, according to Reuters, so it remains to be seen whether the US intends to follow suit. Seventy-six wealthy na-tions are now committed to joining COVAX, Seth Berkley, chief executive of the GAVI vaccines alliance, said.

UK sees highest number of coronavirus cases since mass tests began

The UK has recorded 6,634 new coronavirus cases, the government has announced, making it the highest daily figure since mass testing began. Another 40 people have died within 28 days of testing positive for the virus. The latest figures take the over-all number of confirmed cases to 416,363, and total deaths to 41,902. Meanwhile, people arriving in the UK from Denmark, Slovakia, Iceland and Caribbean island Curacao will need to self-isolate for 14 days from Saturday. After falling from their April peak, confirmed new coronavirus cases in the UK have been rising again since July.

'Lockdown too drastic' says German Health Minister Spahn

German Health Minister Jens Spahn has said that with the knowledge now gained during the pandemic, the coronavirus lockdown would not have had to be so drastic. “Today we can make better decisions between protection and everyday life because we know more, because we have more experience,” he said. We now know, he add-ed, “how we can deal with this ... especially if we wear masks and keep our distance without restrictions.” As a result, Spahn said the lockdown would not have have been so strict: Hairdressers and shops would no longer have been shut down, and there would not have been a ban on visiting nursing homes.

Addressing obesity

The pandemic has been the catalyst behind the UK government's latest drive to tackle the rising level of obesity across the nation. This latest campaign, which is aimed at helping people lose weight, become more active and eat better, is hoping to make an impact on addressing a growing problem which more than ever poses an escalated threat to individuals' health. Since the outbreak of COVID-19, there has been a significantly higher level of deaths amongst obese people who contracted the virus.



A collaborative study between the University of North Carolina, Saudi Health Council and World Bank has now found a 48% increase in death amongst significantly over-weight people who have been afflicted with the coronavirus. The study also reported that the risk of ending up in hospital with COVID-19 increases by 113% for obese people with a 74% increase in their chances of requiring intensive care.

Vaccine confidence boost in UK and Europe, doubts globally

Public confidence in vaccines may be improving in the UK and other parts of Europe but many countries worldwide are seeing growing doubts over immunizations, a new study suggests. Nations experiencing political instability and religious extremism are seeing increasing scepticism over the safety of inoculations, the researchers said, adding that the spread of misinformation is also posing a global threat to vaccination programmes. The study is based on data from more than 284,000 adults across 149 countries in what is thought to be the largest global vaccine confidence survey identifying "hesitancy hotspots". In the UK, confidence in vaccine safety rose from 47% in May 2018 to around 52% in November 2019. In contrast, the researchers said, countries such as Azerbaijan, Afghanistan, Indonesia, Nigeria, and Pakistan showed a fall in confidence in the importance, safety, and effectiveness of vaccines.

Cancer prevention 'like Mrs Columbo'

Concerning the effect that COVID-19 has had and continues to have on the EU and Europe as a whole, and on the incidence of cancer, Health and Food Safety Commissioner Stella Kyriakides said: "COVID-19 has been yet another wake-up call, making us acutely aware of the relationship between our ecosystems and our health and the need to face the facts – the way we live, consume and produce is detrimental to the climate and impacts negatively on our health, and with Europe's future Beating Cancer Plan, we have made a strong commitment to protect the health of our citizens and our planet."

And preventing cancer appears to be emerging as the most popular point of emphasis for Europe's Beating Cancer Plan, with a wry observation on a never-seen character from a 1970s TV detective show. "Prevention is like Mrs Columbo from the 1970s detective show Columbo, joked the Commission's Hana Horka. "Mrs Columbo was frequently invoked, but viewers never saw her.

France at second surge coronavirus wave

France's woes come as the country, after bringing the COVID-19 epidemic largely under control at the end of the spring, is experiencing a second surge. Experts struggle to understand exactly why: Pierrick Tranouez, a member of CoVprehension, a collective of researchers sharing information about the coronavirus with the public, speculates that the country's popularity as a summer tourist destination "could have been a contributing factor, although definitely not the only one."

Whatever the reason, official data show an average of almost 12,000 new infections per day over the past week, twice as high as the UK's new cases over the same period. The figures, by far the highest ever recorded in the country, partly reflect increased testing, with fewer cases going undetected. But COVID-19 is unquestionably spreading again – and fast. The share of tests that turn out positive is four times that tallied in the UK, and rising sharply.

End in sight? (as of this newsletter)

There's an end in sight to the coronavirus pandemic, but people need to hang on a little longer, Italy's Health Minister Roberto Speranza said in an interview with *la Repubblica*. "We need to maintain distancing, wear masks and wash our hands," Speranza added, saying this would not last forever but likely just through the fall and winter. "The key word is proximity: the first place where people are cured should be in the home. We have one of the oldest populations in the world and the numbers of chronically ill patients are increasing, and they aren't treated in hospitals," Speranza added.

Hogan resigns

At the end of August, Irish Trade Commissioner Phil Hogan, was unfortunately forced to resign, following controversy over alleged breaches of COVID-19 guidelines during a trip to his native Ireland, a spokesman for the commissioner said.

Of course, COVID 19 is a very serious issue, but the question is how the guidelines are applied as well as the lowest common denominator in the application of standards. If we go for the lowest commonest denominator and undermining our way of life, are we giving in to the disease in another way, and are we not losing our humanity in not seeing the issue, in this case the person that Phil Hogan is and the office he once represented?

And that is all for now, stay safe and well. EAPM will return soon with our regular update – don't forget to register for the EAPM German EU Presidency Conference, [click here](#), agenda [here](#).

In the news

Digitalisation and COVID-19: The Perfect Storm

<https://www.karger.com/Article/PDF/511232>

Bringing Greater Accuracy to Europe's Healthcare Systems: The Unexploited Potential of Biomarker Testing in Oncology

<https://www.karger.com/Article/FullText/511209>

Seeking response not just in words and plans but in action - EAPM lung cancer report'

<https://eureporter.co/frontpage/2020/09/29/seeking-response-not-just-in-words-and-plans-but-in-action-eapm-lung-cancer-report/>

Digitalization and COVID-19: The Perfect Storm' - EAPM Presidency Conference on the horizon: Register now!

<https://eureporter.co/frontpage/2020/09/28/digitalization-and-covid-19-the-perfect-storm-eapm-presidency-conference-on-the-horizon-register-now/>

Member states and Commission ramp up coronavirus measure; German EU Presidency conference fast approaching

<https://eureporter.co/frontpage/2020/09/25/member-states-and-commission-ramp-up-coronavirus-measure-german-eu-presidency-conference-fast-approaching/>

Report available - Madrid hosted EAPM round table on Tumour Agnostics, innovation, RWE and Molecular Diagnostics which took place at ESMO Congress, 2020

<https://eureporter.co/economy/eu-economy/2020/09/24/report-available-madrid-host-ed-eapm-round-table-on-tumour-agnostics-innovation-rwe-and-molecular-diagnostics-which-took-place-at-esmo-congress-2020/>

German Presidency conference a big date, Commission pushes for healthy planet

<https://eureporter.co/frontpage/2020/09/22/eapm-german-presidency-conference-a-big-date-com-mission-pushes-for-healthy-planet/>

EAPM and ESMO bring innovations to health policymakers

<https://eureporter.co/frontpage/2020/09/18/eapm-and-esmo-bring-innovations-to-health-policymakers/>

State of the Union: Health in the spotlight and the question of translation into health-care system

<https://eureporter.co/frontpage/2020/09/17/eapm-state-of-the-union-health-in-the-spotlight-and-the-question-of-translation-into-health-care-system/>

More funding for health care, French drugs shortages and Cancer Congress on the horizon

<https://eureporter.co/health/2020/09/15/eapm-more-funding-for-health-care-french-drugs-shortages-and-cancer-congress-on-the-horizon/>

Vaccine confidence, preventing cancer, second waves

<https://eureporter.co/health/2020/09/11/eapm-vaccine-confidence-preventing-cancer-second-waves/>

To mask or not to mask, that is the question

<https://eureporter.co/health/2020/09/09/eapm-to-mask-or-not-to-mask-that-is-the-question/>

Confusion reigns over return to work and health-care systems prepare

<https://eureporter.co/eu-2/2020/09/01/eapm-confusion-reigns-over-return-to-work-and-health-care-systems-prepare/>