



Biomedical Alliance in Europe

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1. Virtual roundtable on treatment optimisation to take place 3 February

Our virtual round table with EORTC on treatment optimisation is almost there! On 3 February we will discuss *how current EU policy initiatives can pave the way towards treatment optimisation as part of health systems*. For the occasion, we gathered a panel including high-level experts and Members of the European Parliament to analyse this important and share fresh and diverse perspectives.

Indeed, COVID-19 has demonstrated the urgent need to have a healthcare system that places the patient at the centre and has the ultimate goal to solve clinical issues. This health crisis has put the spotlight on the importance of publicly funded clinical trials in determining which of the many promising treatments deliver real benefits for patients. Treatment optimisation plays an important role in improving the way treatments are utilised in real-world conditions through the conduct of studies. It can provide answers to important aspects relating to the use of novel therapies in real-world settings such as: optimal dose, duration, sequence, combination, and quality of life.

The discussion will be moderated by Peter O'Donnell. It will start with a welcome message from MEP Dolors Montserrat, then Dr. Denis Lacombe (EORTC) and Prof. Guy Brusselle will set the scene with presentations on treatment optimisation in practice. This will be followed by the virtual roundtable with MEP Alessandra Moretti, CML Advocates Network and Patient Advisory Committee member Jan Geissler, Professor of Health Economics Bengt Jönsson and Dr Lacombe and Prof Brusselle. MEP Véronique Trillet-Lenoir will also have a special video message for us. Finally, MEP Maria da Graça Carvalho will close the webinar with final remarks.

The agenda of the webinar is available [here](#).

2. Commission launches new consultation on HERA



The European Commission has launched a consultation on the inception impact assessment for the new the Health Emergency Response Authority (**HERA**). The [consultation](#) is open on the website of the Commission until 24 February and the BioMed Alliance will prepare a response.

You may remember that we informed you about the plans for this new authority in earlier editions of this newsletter (see e.g. our [briefing](#) on the EU Health Union). HERA is supposed to enhance resilience against cross-border health threats and was described by the Commission as the European equivalent of the US Biomedical Advanced Research and Development Authority (**BARDA**). HERA's role would be to support the EU's capacity and readiness to respond to cross-border threats and emergencies. According to the proposal, it should provide for 'the full array of serious cross-



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border threats to health' and would 'provide added value by addressing the challenges that the Member States cannot efficiently and effectively address on their own'. It will support coordination of operations across the whole value chain from strategic investments for research to the distribution and use of medical countermeasures.

The Commission will launch a broader public consultation in March and intends to present the proposal in the second half of 2021. The authority would then start operations in 2023.

3. Date BioMed Alliance GA announced



The BioMed Alliance Board of Directors has confirmed the date for the 2021 General Assembly, which will take place on 30 November. While the Spring Meeting on 20 May will certainly take place online, we will see if we can organise the General Assembly face-to-face (if circumstances allow it). We will follow-up in due time with more information about both meetings.

4. BioMedScape Update



You may remember that the BioMed Alliance organised a webinar on 8 December to introduce members to a new project we would like to put into motion: BioMedScape. This project is based on CardioScape, a study of the European cardiovascular research landscape which aimed to establish a reliable and continuously up-to-date database of project funding in cardiovascular research in Europe.

The idea was to develop CardioScape into a BioMedScape project with the goal to extend the funding database and analysis tool to other biomedical disciplines. After the webinar, we launched a call for members of the soon to be formed BioMedScape Working Group and 19 organisations are interested in joining the Working Group. The first meeting of the Working Group will be organised end of February or early March and aims to identify the organisation, next steps and possibilities for attracting the necessary funds to develop BioMedScape.

5. Consultation on European Health Data Space



The European Commission launched a consultation on the roadmap for the new regulation for the European Health Data Space that is scheduled to be adopted during the 4th quarter of this year. The Roadmap provides an overview of the context, the problems the initiative aims to tackle, objectives, policy options and the impact and will guide and feed into the upcoming legislative proposal.

The proposal seeks to address issues related to access to and exchange of health data for healthcare delivery, scientific research and innovation, policy making and regulatory activities. It will be addressing governance issues, the fragmentation of the implementation of the GDPR and technical standards and specifications. It will also look into data access infrastructures and the role of national digital health bodies and sectoral bodies dealing with secondary use of health data, and how they can be brought together at European level. The proposal will be using the experience of existing initiatives including the 1million genome project. It will also be addressing the health specific aspects of AI, especially in terms of regulation of liability.

While the proposal aims to facilitate data exchange and enhance access to data for research and policy making, it will also increase patient access and control over their own data.



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The BioMed Alliance has prepared a response to this roadmap. Other consultation activities are foreseen in the coming months and the proposal for this initiative is set to be published at the end of 2021.

The consultation is open until 3 February and available [here](#).

6. UK Participation in Horizon Europe after Brexit



As the EU-UK trade and cooperation agreement has finally been concluded on Christmas Eve, we can start reflecting on the possible consequences for cooperation in health and science in Europe.

The full details still have to be agreed on, but the EU-UK trade and cooperation agreement already gives an idea of what the UK's future participation in Horizon Europe may look like. According to the deal, the United-Kingdom will become an "associate" member of Horizon Europe, which means it will continue to pay and participate in Horizon Europe. British researchers will therefore be able to keep applying to calls and participate in European research projects.

The United-Kingdom and the European Union also agreed on the recognition of each other's quality standards and inspections of medicines to avoid extra safety checks at the borders. But this recognition mechanism does not encompass other stages of medicines' life cycle such as batch testing or regulatory approvals, making it illegal to sell medicines on the European market that have only been tested in the UK.

Last but not least, UK-based researchers will now have to request a visa to work in the EU for more than 90 days. Likewise, EU scientists will have to apply to the new UK immigration system, like any researchers from the rest of the world.

7. Upcoming

- The BioMed Alliance is organising a **virtual roundtable** on 3 February with EORTC on 'How can current EU policy initiatives pave the way towards treatment optimisation as part of health systems?'
- The **Spring Meeting** will take place online on 20 May
- The **General Assembly** will be organised on 30 November.





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8. Members News

This section includes articles submitted by BioMed Alliance Members themselves. If you have an item that could be relevant to other members and it is in line with the BioMed Alliance’s policy work, then please send it to us by the 21st of each month. Thank you for your submissions!

EBC launches statement on the impact of COVID-19 on brain health

**EBC Statement:
The Impact of COVID-19 on Brain Health**
January 2021

The COVID-19 pandemic had a major impact on the health and wellbeing of European citizens. As stressed in many scientific articles and in most of the health authority reports, the impact of COVID-19 on brain health during the last months has been a major and dramatic one with severe mental and neurological consequences. Like other organisations in the health space, EBC has taken the time to observe the progress of the virus over the last months and gather concrete information made available by ongoing research. As the EU begins administering the vaccine, one year of the COVID-19 pandemic must also serve as a wake-up call to ensuring the public response is not only limited to vaccination but also takes long-term consequences in mind. Read the full EBC statement [here](#).

EASL’s Patient Synergies Roundtable Discussion on liver cancer: Improving the lives of Cancer Patients



On the occasion of the [Digital Liver Cancer Summit 2021](#) and the World Cancer Day, EASL is organizing a Patient Synergies Roundtable Discussion on liver cancer on Thursday 4 February from 14:00-16:00 CET. The roundtable aims to identify the needs of liver patients and their families, and the best ways to accompany them in their journey and will take the form of an open interaction between scientists and patient representatives. The discussions will focus on three topics: liver cancer early diagnosis and risks factors, COVID-19 challenges and liver cancer care, and the inequality of cancer burden in different European countries. The Roundtable will provide the chance to have an open interaction between scientists and patient representatives, and could therefore also be interesting for a broad range of participants.