



Biomedical Alliance in Europe

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1. Treatment optimisation must be better embraced in our health system

On Wednesday 3 February, the BioMed Alliance and EORTC organised a webinar around the central question: “How can current EU policy initiatives pave the way towards treatment optimisation as part of health systems?”. This is a pressing question as there currently is a gap in the research and development process for innovative treatments that results in a lack of information relating to the use of novel therapies in real-world settings.

The EU roundtable hosted by MEP Maria da Graça Carvalho and MEP Dolors Montserrat was moderated by Peter O’Donnell and brought together a large number of stakeholders. The event gathered a high-quality panel including Dr Denis Lacombe (EORTC Director General), Professor Guy Brusselle (ERS, Gent University), MEPs Alessandra Moretti and Véronique Trillet-Lenoir, Jan Geissler (CML Advocates Network and the Patient Advisory Committee), and Bengt Jönsson (Professor of Health Economics), to share their perspectives on this important topic.

MEP Dolors Montserrat opened the webinar mentioning that the EU is empowering a new fight against cancer with the new Cancer Plan (which was presented the day of the webinar), and highlighted how treatment optimisation is a key element to fight cancer placing patients’ needs at the center.

Dr Denis Lacombe explained that the development process of drugs and therapies needs to be re-engineered to ensure the best use of these drugs and therapies in practice. Professor Guy Brusselle also underlined the large research gap existing between pre-approval development of medicines and their post-approval use in real life. The patient should be at the center and Jan Geissler therefore urged regulators and policy makers to facilitate patient involvement, and highlighted how treatment optimisation could help ensure their preferences are better taken into account.

Finally, MEP Maria da Graça Carvalho brought the webinar to an end with some final remarks, saying that the European Parliament will continue its support for better and more effective health policies at EU level.

2. BioMed Alliance welcomes HERA inception impact assessment



The BioMed Alliance has prepared a response to the consultation on the inception impact assessment for the new Health Emergency Response Authority (HERA) with its Board of Directors.

HERA is supposed to enhance EU 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).



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The BioMed Alliance welcomes HERA and believes it must receive the necessary support to properly fulfil its intended purposes. We argue that stakeholders should play a leading role in its implementation and HERA must be embedded in a forward-looking and research-driven environment.

The BioMed Alliance's response to the consultation can be found [here](#).

3. Proposal for European Partnership for Health Innovation released



The European Commission has published the new proposal for the European Health Initiative (IHI). The public-private partnership for health is the successor of IMI with an expanded scope including multiple health industry stakeholders representing pharmaceutical, biotech and medical technology companies. It is co-funded by the European Commission on the one hand and EFPIA, MedTech Europe, COCIR, EuropaBio and Vaccines Europe on the other. The BioMed

Alliance has followed the development of the partnership very closely.

Objectives

The new partnership will contribute towards the creation of a Union-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, foster the development of safe, effective, people-centred and cost-effective innovations that respond to strategic unmet public health needs and drive cross-sectoral health innovation for a globally competitive European health industry.

Structure & Stakeholder Involvement

The partnership will be overseen by a Governing Board (consisting of the funding members) which takes strategic decisions and has the final say in matters around the partnership. In addition, both a States' Representatives group and an Innovation Panel will be established. The Innovation Panel includes stakeholders and will advise the governing board about scientific priorities, the draft work programme, the planning of additional activities, the setting up of advisory groups on specific scientific priorities and the creation of synergies with other Horizon Europe activities. The Innovation Panel has an advisory role, and the final decision-making power remains with the Governing Board and thus the funders of the partnership. The governing board also establishes the specific criteria and selection process to appoint the stakeholder representatives.

The Innovation Panel will be composed of:

4 Commission representatives

4 representatives of industry members

2 representatives of States Representatives' Group

2 representatives of the scientific community

6 permanent panellists, ensuring appropriate representation of all health stakeholders

Executive director and a representative of the programme office



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Case studies

The European Partnership for Health Innovation also published case-studies on its website of research challenges for which cross-sectorial collaboration is needed. As you may remember we promoted the call for the collection of case-studies and the example submitted by the European Association of Urology was published on the partnership website. You can find the case-studies [here](#).

Next steps

The proposal for the IHI will now be discussed in the Council of the EU and the final version of the Strategic Research Agenda and the Work Programme are expected shortly. We will keep you posted on new developments and once more information becomes available on the selection of stakeholders for the innovation panel.

4. New workshop on health in Horizon Europe



On 11 March, the National Contact Point (NCP) Brussels is organising a webinar about health-related funding opportunities under Horizon Europe “Health across Horizon Europe”. The goal of this workshop is to help stakeholders to better assess funding opportunities from Horizon Europe and to prepare their proposals.

The webinar is open for Brussels-based applicants on Horizon Europe and provides an excellent opportunity to get the necessary knowledge to effectively navigate health funding opportunities in the programme.

More information on the webinar is available [here](#).

5. Commission launches Europe’s Beating Cancer Plan



On 3 February, the European Commission launched the Europe’s Beating Cancer Plan to tackle the growing challenges in cancer control, prevention, treatment, and care. The plan is one of the key pillars of the European Health Union and is built around four key action areas; prevention, early detection, diagnosis, and treatment, and improve quality of life of cancer patients and survivors. The Cancer Plan will deploy actions addressing cancer through the whole range of initiatives and funding instruments from the European Commission, including the EU4Health programme, Horizon Europe, and the Digital Europe programme, with a total budget of €4 billion.

6. The GDPR & Health data



The European Commission published a new study on the assessment of EU Member States’ rules on the use of health data in the light of the General Data Protection Regulation (GDPR). It aims to identify the differences and elements that might affect the cross-border exchange of health data in the EU and its impact on healthcare, health research, innovation and policy making. The study highlights the divergences in the implementation of the GDPR in Member States in the area of health, leading to a fragmented approach in health data processing

for health and research within the EU. The study also underlines the importance to take into account the interests of patients when processing health data, and especially to give them the full capacity to exercise their health data related right.

Finally, the study indicates a number of legal and operational suggestions to support the development of the European Health Data Space. A more harmonised approach is indeed needed in terms of technical infrastructures, data-quality and acquisition, digital skills and capacity building for primary



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and secondary use of health data. More guidance is being developed at the moment, and the TEHDAS Joint Action is developing a Code of Conduct for secondary use of health data.

For further information, you can access the study [here](#).

7. European Patient Ombudsman Award for the Best Medical Practice



The International Council of The Patient Ombudsman and the European Medical Association launched a call for the European Patient Ombudsman Award to recognize European doctors who have made significant contributions and efforts that have influenced positive change in the COVID-19 pandemic. The goal of this award is to acknowledge their struggles and achievements while battling the pandemic in these unprecedented times while risking their own health to help save lives and preserve patients' quality of life. The deadline to nominate is March 31, and the award ceremony and inauguration will take a place at the European parliament, at "The White-Coats Day" conference planned in May 2021.

You can find more information about the award [here](#).

8. Upcoming

- The first meeting of **BioMedScape Working-Group** will take place on 22 March
- The **Spring Meeting** will take place online on 20 May
- The **General Assembly** will be organised on 30 November.





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9. 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!

EASL: Position Statement on COVID-19 vaccination prioritisation for specific patient groups



Early February, EASL published a position paper on the use of COVID-19 vaccines in people with chronic liver diseases, hepatobiliary cancer and liver transplant recipients in the Journal of Hepatology. Now that vaccinations are being administered, it is essential that the population and particularly high-risk groups are vaccinated as soon as possible.

People with chronic liver disease (CLD) are at increased risk for a severe course of COVID-19, especially those with cirrhosis in advanced stages, with hepatobiliary cancer, and transplant patients, whether they are candidates for liver transplantation or have already undergone transplantation. The statement aims to inform policymakers, healthcare professionals, patients, and affected communities of the risks for this specific patient group and argues that they should be priority candidates for receiving the vaccine. More information on the EASL statement is available [here](#).

ESC: Cardiovascular Realities 2020



The European Society of Cardiology (ESC) recently published Cardiovascular Realities 2020, a publication providing arguments for increasing action to support cardiovascular health policy.

The publication includes comprehensive cardiovascular data from the ESC Atlas of Cardiology covering risk factors, health behaviors, access to healthcare and the cost of cardiovascular disease.



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Cardiovascular Realities is an interesting advocacy tool aiming to help countries and stakeholders involved in healthcare policy and budget allocation to meet WHO sustainable development targets on non-communicable diseases, and to identify which areas of intervention require greater attention. Read the full publication [here](#).

EBC: Save the date for the MULTI-ACT Final Conference!



The EBC is part of the MULTI-ACT consortium which organises the [MULTI-ACT Final Conference](#); “The MULTI-ACT model: the path forward for participatory governance in health research and innovation”, that will be held virtually on 23 March 2021 from 14:00-17:00 CET.

The MULTI-ACT consortium is an EU funded project aiming to increase the impact of health research on people with brain disease. It involves multidisciplinary stakeholders and the main outcomes of the project include the development of a governance model, a roadmap for patient engagement and impact indicators along five dimensions to foster stakeholder engagement in health research and innovation. The consortium also led to the creation of an online toolbox that will be made available to organisations willing to conduct health research with a multi-stakeholder and co-accountable approach. While the project focusses on brain research, conclusions can be relevant for the engagement of actors and stakeholders in health research in general registration to the conference will be opened soon.