



Biomedical Alliance in Europe

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1. State of the European Union: health at the centre



During the State of the Union Address on 16 September, European Commission President Ursula von der Leyen announced her plans for the coming year and the recovery from the pandemic. A key element of her vision is a stronger EU Health Union.

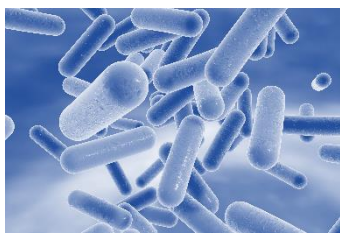
The BioMed Alliance very much welcomes President Von der Leyen’s commitment to strengthen the European Health System. While we have to wait to see the exact content of the proposals; it is a promising development. We especially support the proposal to establish a European agency for biomedical advanced research & development, which appears to be in line with BioMed Alliance calls for more coordination in health research.

Main elements of the State of the European Union Speech:

NextGenerationEU is to play a key role in post-pandemic recovery	President Von der Leyen argued that the new recovery instrument, NextGenerationEU will play a key role in the recovery from the COVID-19 pandemic and will work both on recovery and enhancing resilience.
Building a Stronger European Health Union	The Commission proposed to strengthen health related institutions. While health is currently mainly a member state competence, von der Leyen proposed to ‘discuss the question of health competences’ at the Conference on the Future of Europe (2-year conference seeking input from citizens on the future of the EU related to policy and institutional matters).
Make the new EU4Health Programme future-proof	President Von der Leyen mentioned she is ready to ‘fight for more funding’ for the new health programme in discussions with the Council.
Strengthen crisis preparedness and management	President von der Leyen announced that the Commission will propose to ‘reinforce and empower’ the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC).
Build an agency for biomedical advanced research and development	The President argued that the Commission will build a European BARDA – an agency for biomedical advanced research and development. This new agency would support capacity and readiness to respond to cross-border threats and emergencies.
Organisation of a Global Health Summit next year	A Global Health Summit will be conveyed next year to identify and address the lessons learned at global level.



2. BioMed Alliance calls for progress on EU-level HTA



In a new statement published on 3 September, the BioMed Alliance calls on the German Council Presidency to guide Member States into adopting a position on the Regulation for Cooperation on Health Technology Assessment as soon as possible. The statement also recalls a previous BioMed Alliance statement from 2019 calling for the proposal to swiftly be adopted. Since then, limited progress has been

made.

Cooperation on HTA has numerous benefits for the European health system and could enhance coordination, reduce duplication, improve efficiency, reduce costs and lead to better treatments for patients. The coronavirus crisis has illustrated the importance of having a legally sound and functioning HTA system in place that could help the EU to prepare for future health crises.

Read the statement [here](#), and our previous statement from 2019 [here](#).

3. Reducing bureaucracy in clinical trials: now is the time!



Medical societies and patient advocates across disciplines call for urgent action to make clinical trials less bureaucratic and more patient-centred, efficient and cheaper.

Excessive administrative demands lead to rising costs and complexity, stagnation of clinical research in Europe, fewer academic clinical trials and limited access to innovative treatments. Unnecessary, inefficient, overly complex or ambiguously worded regulations, guidelines, safety reporting requirements and informed consent procedures pose a threat to exactly that which they were designed to protect: the quality of clinical trials and the safety of patients.

That more flexible, risk-based and pragmatic regulation is possible, without compromising on either quality or safety, was demonstrated by the guidance issued by European regulators on the management of clinical trials during the Covid-19 pandemic. A substantial and structural reduction of bureaucracy in clinical trials must be the shared goal of clinical researchers, patient advocates, policymakers and regulators at EU and national levels, ethics committees and the pharmaceutical industry.

At stake is the efficiency and affordability of clinical trials, and with it the quality of future health care and – ultimately and most importantly – patient safety.

The BioMed Alliance Clinical Trials Task Force will organise a meeting on 1 October to discuss the next steps and to formulate proposed solutions. Afterwards, a multi-stakeholder roundtable will be planned with regulators and industry.

Read the statement [here](#).



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4. EU-level COVID-19 Skills Preparation Course launched



COVID-19 Skills Preparation Course

An excellent example of how medical societies explore new ways of cooperation with policy makers and the Commission in close partnership is the new C19-SPACE. In this programme, BioMed Alliance member ESICM works with the Commission to organise continuing medical education activities enhancing resilience against health threats and together they can reach a broad audience.

BioMed Alliance member ESICM is undertaking the [training programme](#), financed by the European Commission, of a multidisciplinary pool of healthcare professionals supporting and assisting ICUs in times of need due to the COVID-19 pandemic. The training will provide intensive care medical skills to doctors, nurses and healthcare professionals not regularly working in ICUs and will be available cost-free across the EU and UK until the end of 2020. Registration is currently open and more information is available [here](#).

5. New innovation forum to be launched under Horizon Europe



The European Commission is planning to set up a new forum under the European Innovation Council bringing together entrepreneurs, policymakers and academia. The idea was announced during the Research & Innovation Days in the end of September and the new forum intends to facilitate innovation in Europe. The plan is still in the early stages, but we will keep you posted as more information becomes available.

6. Upcoming

- We are organising another call of the **Policy Officers Committee** on 23 October.
- The second **EU Health Summit** will take place online on 26 October 2020. This event is organised by the [EU Health Coalition](#), of which the BioMed Alliance is an active member.
- On 28 October, the BioMed Alliance **Taskforce on Clinical Trials** will organise a meeting on treatment optimisation
- The **General Assembly** takes place online on 26 November 2020.



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7. Members News

The new section 'Members News' will showcase the activities of medical societies in articles submitted by BioMed Alliance Members. 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 - Patients with liver conditions and transplants suffer COVID-19 setbacks



The European Association for the Study of the Liver (EASL) identified several actions urgently needed to serve liver and transplant patients affected by COVID-19, that are relevant to larger health issues too. Authors of the [EASL-ESCMID Position Papers](#) note that the pandemic resulted in strained healthcare services and less sustained monitoring of patients.

The Position Papers call for research, such as the [EASL-supported survey](#) to assess how the pandemic affects various aspects of liver transplant care and practices, and [COVID-Hep registry](#) to better identify patients at higher risk, including those with obesity and cirrhosis. The Papers call for the resumption of targeted treatment and surveillance for patients to prevent a decline in the standard to care. New strategies that evolved during this time, such as telemedicine, should be used. This is in line with the BioMed Alliance call for progress on [EU-level Health Technology Assessment \(HTA\)](#) noting that it is essential for new health approaches to be used through and beyond the pandemic.



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EULAR – EULAR Brussels Forum

eular

fighting rheumatic & musculoskeletal diseases together

To mark World Arthritis Day, a global awareness day held on 12 October each year, EULAR seeks discussion with members of the EU policy arena, helping to create and maintain awareness around topics directly concerning people with rheumatic and musculoskeletal diseases (RMDs) in society. The event will explore the challenges faced by people living with RMDs, and the practical and policy measures that can meet their employment needs. It takes place against the backdrop of important policy developments at EU level, including ongoing negotiations over the COVID Recovery Plan, as well as the contents of the new Pharmaceuticals Strategy for Europe and Disability Strategy. More information is available [here](#).

EBC – Registration is open for the Brain Innovation Days launch



Facilitating innovation in health research to provide better care to patients is a high priority both at EU level and for the BioMed Alliance. It is encouraging to see that our members carry on their important activities online to continue supporting and promoting innovation in health research. The European Brain Council for example announced with beLean.net the digital launch of the [Brain Innovation Days](#), on 13 October 2020 at 12:30-14:30. This launch kicks off one full year of brain innovation, with a number of digital sessions to follow in 2021.

The lunchtime interactive session will fall under the overarching theme, "Disrupt and rewire: how brain innovation is changing Europe" and will bring together representatives from the European Commission, the European Medicines Agency, the Innovative Medicines Initiative and the European Parliament alongside key opinion leaders, researchers, start-ups, clinicians and more to explore and answer the question: why is brain innovation important and how is it changing Europe and the world?

Register for free here: <https://live.eventtia.com/en/3fbc>

EAS- Access EAS Congress 2020



In the spirit of cooperation, and as other societies have done, the European Atherosclerosis Society provides access to its virtual 88th Congress, EAS 2020, taking place 04-07 October. In response to the challenges facing the scientific and medical community at present, the Society's Executive have taken the decision to waive Congress registration fees for 2020.

EAS brings together investigators from diverse fields, including: cardiology & vascular medicine; lipidology; endocrinology, diabetes & metabolism; internal medicine; molecular biology; biochemistry; pharmacology; and nutrition & diet. We welcome scientists and researchers from these areas, from around the world – old friends and those new to our community – to join us for our Virtual Congress.

For CME-programme details, visit the Congress website: <https://eas2020.com>

Free registration at this link <https://eas2020.com/registration/register/>