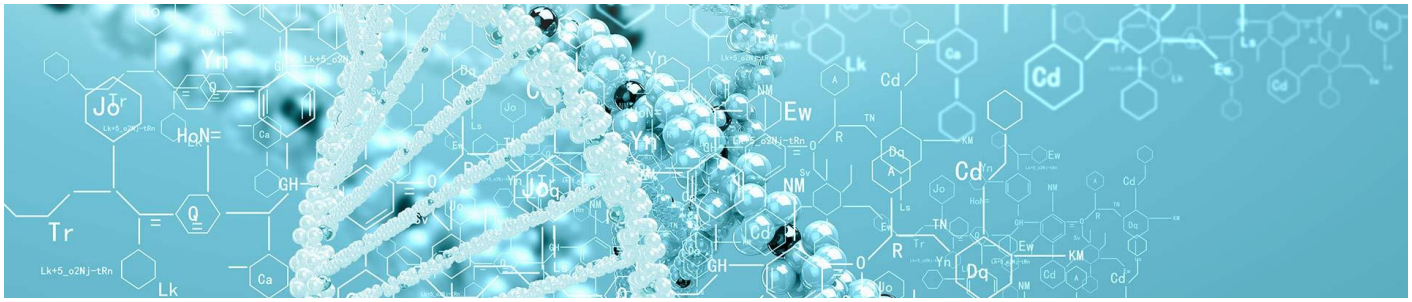

Biomedical Alliance in Europe

UPDATE JUNE

2021

Highlights:

1. Implementation IVDR: successful advocacy results

At the end of May, laboratory experts from the BioMed Alliance IVD Working Group released a new statement to raise awarness about the state of play of the In-Vitro Diagnostic Regulation (IVDR) implementation and to alert stakeholders and decision makers that urgent action is needed to prevent a collapse of the diagnostic sector. The statement was largely disseminated among our member societies and their national constituencies, on social media and EU platforms and was sent to several policy makers.

The advocacy work that the BioMed Alliance did around this initiative showed promising results; we managed to mobilise a number of our members and to put pressure at the level of the Member States. The issues around the implementation and the need for contingency planning were subsequently discussed during the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) meeting on 15 June. The European Commission has now the mandate to explore contingency planning for the IVDR. BioMed Alliance will continue voicing the concerns of the laboratory sector, for instance in the next MDCG meeting where the state of play of the IVDR and potential contingency planning will be discussed.

We will keep you updated on the next steps and outcomes, in the meantime, the statement is available to read here.

2. New Taskforce on Health Data holds its first meeting in July

Health data is a hot topic at EU level, and with the number of initiatives steadily increasing there is an opportunity for the medical & research community to provide input. European Union bodies have recently intensified discussions on the GDPR application in health and the European Commission announced new initiatives including the European Health Data Space, the 1 million genomes project, and a new regulation on Artificial Intelligence.

The BioMed Alliance was recently accepted as a registered stakeholder in Work Package 5 and 7 of the Joint Action Towards the European Health Data Space (TEHDAS) which aims at developing principles for the secondary use of health data. Our role as a stakeholder is to provide feed into the work of the Joint Action by replying to surveys and contributing during meetings and workshops.

To facilitate joint advocacy efforts on health data sharing and be able to quickly and efficiently contribute to the Joint Action, we put together a group of experts with experience in health data sharing. This new taskforce is intended to gather input from our members and form a collective position while ensuring that the experiences of researchers and medical societies are considered in the development of the EHDS and other relevant EU health data initiatives. A large number of societies has already expressed interest and others are still welcome to join.

TEHDAS is organising regular meetings in the coming period and actively launching surveys, therefore we decided to hold a meeting before the summer for initial discussions on how to organise our participation in the Joint Action and ensure we are collectively contributing in an impactful manner. The first meeting of the Expert Group will take place on 8 July from 9.00-10.00 CEST. If your organisation would still like to attend the meeting or join the taskforce, then please contact us as soon as possible.

3. BioMed Alliance at the French National Assembly

As part of our partnership with EIT Health, BioMed Alliance was invited to participate in a roundtable discussion at the French National Assembly on innovation and digital health skills. The roundtable on 7 July is part of a series of workshops on Health organised by EIT Health France and targeted at policymakers in France to highlight the need for talent attractivity and for promoting skills in the digitalisation of health. Professor Elizabeth Macintyre will represent BioMed Alliance at this workshop and address the need for digital skills in health from a European perspective, underlining the challenges and opportunities experienced in the medical sector.

4. Work Programmes for Horizon Europe published

The European Commission has published several Woking Programmes for different health related elements within Horizon Europe including the Health Cluster 2021-2022 Work Programme, the Work Programmes for the Missions, the EU4Health Work Programme for 2021 and the Marie Skłodowska-Curie Actions. The work programmes provide an overview of the upcoming calls and their deadlines for each of these initiatives and there are ample opportunities for health and biomedical research. There are multiple calls for 2021, and the first calls for 2021 have already opened on the Commission's Funding and Tenders Portal and the first deadlines are in September.

The first draft Strategic Research and Innovation Agenda of the Innovative Health Initiative (IHI) was also published and is intended to guide the activities of this successor of the Innovative Medicines Initiative (IMI) in the coming years. The legislative proposal establishing partnerships under Horizon Europe is currently being discussed. Once the IHI is officially established, the draft Strategic Research and Innovation Agenda will be formally adopted by the IHI Governing Board. We will keep you posted on any new developments and will inform you once more information is provided on the selection of the new stakeholder panel, the 'Innovation Panel'.

Our member ESE has also created a nice information page on European Research Funding including a page on upcoming relevant calls.

Horizon Europe Health Cluster WP 2021-2022	Cancer Mission WP 2021-2022	EU4Health WP 2021	IHI Strategic Research & Innovation Agenda
•The calls are divided in 6 destinations •The Work Programme is available here	•The Work Programme of the Missions is available here	•The calls are divided in 5 focus areas •The first annual proramme is available here	•The first draft Agenda is available here

5. Horizon Europe Info Days 2021 are coming!

The first Horizon Europe Info Days will take place from 28 June to 9 July and aim to provide information and necessary clarifications about Horizon Europe, its different Clusters and upcoming calls. This 10-day event will be the opportunity for prospective applicants and EU

research and innovation stakeholders to get more information on the upcoming calls, the processes, and the main funding instruments of the new programme, as well as to directly ask questions.

The Horizon Europe Info Days will address each of the 6 clusters of Horizon Europe, as well as the European Research Area, the Research Infrastructures and the Marie Skłodowska-Curie Actions. The **Info Day on Cluster 1 Health** will take place on 2 July and consists of different sessions on the 6 destinations in the Cluster with Q&A sessions. The Info Day on Cluster 1 Health is open for participation without prior registration.

For more information, please find the page of the event here.

6. Agreement reached on health technology assessment proposal

After 3 years of negotiations, the European Parliament and the Council reached a political agreement on 22 June on the Health Technology Assessment Regulation.

The regulation will help enable joint scientific assessments of medicines and medical devices at EU level, supporting Member States to take more timely and evidence-based decisions on patient access to their healthcare systems. The new framework will also, in addition to work on joint clinical assessments, cover joint scientific consultations, the identification of emerging health technologies, and voluntary cooperation.

The Regulation will replace the current system of EU-funded project-based cooperation between Member States on health technology assessment with a permanent framework for joint work. Regular consultation between the Coordination Group and stakeholders is foreseen and a new stakeholder forum will also be established facilitating this dialogue.

The BioMed Alliance published two statements in 2019 and 2020 expressing their support for health technology assessment. Ahead of the final trilogue meeting, we have also contacted key health attachees to reiterate the support of the scientific community for HTA following advocacy efforts from the ESC.

The Regulation will now have to be formally adopted by the Council and the European Parliament before it can enter into force.

7. Upcoming

- The next call of the **Policy Officers Committee** will take place on 30 June
- The first meeting of the new **Taskforce on Health Data** will be organised on 8 July
- The next teleconference of the **Clinical Trials Taskforce** takes place on 12 July
- The next meeting of the **Regulatory Affairs and Medical Devices Taskforce** is scheduled on 13 July
- The BioMed Alliance will organise an **internal webinar** in September on maximising the impact of advocacy strategies, more information will follow
- The **General Assembly** will be organised on 30 November. Depending on the situation with the pandemic, we hope to hold the GA as a physical or hybrid event. We will come back to you with more precise details on the organisation of the GA by the end of the summer.

Biomedical Alliance in Europe

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!

EASL: The International Liver Congress – Beating Liver Disease together

The European Association for the Study of the Liver (EASL) organised the International Liver Congress (ILC) 2021 on 23-26 June. During the congress, EASL launched an Open Letter: 10 Asks to Improve Liver Cancer Care in Europe. EASL is addressing the European Institutions with 10 demands to reverse the curve of the rising liver cancer mortality by implementing actions via Europe's Beating Cancer Plan and EU4Health Programme.

The Open Letter calls to take action at various levels from prevention and awareness-raising to the implementation of structured patient pathways. The call for action is relevant for numerous chronic diseases. For instance, EASL calls for the implementation of preventive measures as evidence-based strategies for alcohol and obesity, Hepatitis B vaccination, lifestyle interventions, risk education, and consumer labelling of alcohol as a carcinogen. Thus, EASL is inviting all partners to support the letter here.

EASO: Embedding the narrative on obesity as a chronic disease

The European Association for the Study of Obesity (EASO) is conducting a capacity-building programme on embedding the narrative on obesity as a chronic disease following the recent categorisation of obesity as a chronic disease by the European Commission.

To tackle this issue, EASO is organising several activities. On 2 July will take place a Policy Stakeholder Session that will look at how to make the most of this recent categorisation of obesity as a chronic disease and to ensure policy is put into practice. EASO is also organising a series of training workshop on Advocating on Obesity starting from 5 July and aiming to

draw on research and good practices from across Europe to explore how to engage with policymakers and other stakeholders to shift the dial on obesity policy.

This capacity-building programme is a good opportunity for all members and experts to better apprehend the advocacy process in general by breaking the advocacy process down into key steps, from identifying and prioritising key issues, to implementing an advocacy action plan. The goal of the workshop series is to better understand audiences and tailor the messaging to engage them and inspire their support.

More information is available here, please note that registration is open until 30 June.

EULAR: Achieving agility in Advocacy

eular
EUROPEAN ALLIANCE OF ASSOCIATIONS FOR RHEUMATOLOGY

Professor Ian McInnes, past president of the European Alliance of Associations for Rheumatology (EULAR) wrote an article reflecting the journey to-date EULAR has taken since 2016 in terms of communication and advocacy. The article published in the Association Meetings International (AMI) magazine shows under the form of a case study how EULAR built its communications and advocacy functions from the ground.

Profiling rheumatic and musculoskeletal diseases in the political arena requires robust yet agile advocacy efforts supported by dynamic communications approaches. With communications approaches speeding up and the COVID-19 pandemic adding-in further complexity, keeping ahead of the digital transformation is more important than ever. The article is providing a good insight into how a medical organisation can build and streamline its communications and advocacy framework.

You can read EULAR's journey here.

EBC: new policy paper "RETHINKING MS in times of COVID-19"

Following the World Multiple Sclerosis Day on 30 May, the European Brain Council (EBC) released its new policy paper "RETHINKING MS in times of COVID-19", highlighting how the lives of people living with Multiple Sclerosis (MS) have been affected by the pandemic. This paper is part of the main report "RETHINKING MS in Europe", a research-driven project offering tangible policy changes to improve the lives of people living with Multiple Sclerosis across Europe. At this occasion, EBC also launched a virtual exhibition "Living with MS during COVID-19 A case for rethinking MS care in the EU". The exhibition shows portraits of people supporting EBC's RETHINKING MS call, including people living with MS, clinicians, care givers, policymakers and industry representatives, who want to make a difference in how MS care is delivered in Europe.

The paper and virtual exhibition provide concrete and tangible testimonies from clinicians, MS patients, patient advocates and pharma representatives, impacted by the disruption in care but which proved both an obstacle and an accelerator for the implementation of good practices.

The EBC paper is available here, and you can view the virtual exhibition here.