

Biomedical Alliance in Europe

# UPDATE APRIL

2021

## Highlights:

1. ESR joins BioMed Alliance ..... 1
2. CORE-MD: kick-off meeting launches the work on the project ..... 1
3. STOA: BioMed Alliance Members call for evidence-based EU health policy. 1
4. BioMed Alliance joins the TEHDAS Joint Action as a stakeholder ..... 2
5. Don't miss your chance to register for the Spring Meeting ..... 2
6. BioMed Alliance joins the call for an extended mandate of the ECDC ..... 3
7. Upcoming ..... 3
8. Members News ..... 4



## 1. ESR joins BioMed Alliance



The BioMed Alliance continues to grow and is excited to welcome the European Society of Radiology (ESR). The ESR joined in April and is the 36<sup>th</sup> member of the Alliance.

[ESR](#) was founded in 2005 by the merger the European Congress of Radiology and the European Association of Radiology to strengthen and unify European radiology and safeguard its general interests. The ESR's mission is to serve the health care needs of the general public through the support of science, teaching and research and the quality of service in the field of Radiology in all European countries gathering around 122,343 affiliated members. We look forward to a fruitful collaboration.

## 2. CORE-MD: kick-off meeting launches the work on the project



The kick-off meeting for the CORE-MD project took place on 16 April 2021, officially launching the work on the project. The Consortium is composed of 22 partners, including BioMed Alliance and is led by ESC in close partnership with EFORT. We now officially started work on the 3-years project funded by Horizon 2020, which aims to contribute to evidence-based decision making for high-risk medical devices, notably by translating expert knowledge into advice for regulatory guidance and building expertise in the clinical community. The first steps of the project will be to review the methods used in clinical trials for evaluating high-risk medical devices.

BioMed Alliance is very enthusiastic to start the work on Work-Package 4 'Networking & Community Building', that we are co-leading and which has the objective to establish methods for networking between notified bodies and regulators with clinical and scientific experts. The BioMed Alliance Taskforce on Regulatory Affairs & Medical Devices will play an important role and will generate input feeding into the project.

*This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965246.*

For more information, the press release is available [here](#).

## 3. STOA: BioMed Alliance Members call for evidence-based EU health policy



The workshop "The need for better EU policies for health" was organised on 22 April by the European Parliament Panel for the Future of Science and Technology (STOA), in cooperation with the BioMed Alliance and with the support of the European Society of Cardiology (ESC), the European Haematology Association (EHA) and the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM).

The workshop was a success, with more than 200 registered participants, and gathered prominent experts to discuss questions related to medical devices and in-vitro diagnostics, health data and evidence-based policies. BioMed Alliance President Prof. Wilfried Ellmeier opened the first session that was dedicated to the new In-Vitro Diagnostic Medical Devices Regulation and its impacts on patients and on the health system. The panellists of this session, including Prof. Elizabeth Macintyre



## Biomedical Alliance in Europe

(BoD Member and chair of the IVD WG), raised awareness on issues related to the implementation of the IVDR that need to be urgently addressed. Indeed, with the IVDR application date only one year away, much still needs to be done to ensure the diagnostic sector is fully prepared.

The second session was chaired by Prof. Alan Fraser Chair of the BioMed Alliance Medical Devices Taskforce and addressed the question of the need for more evidence-based EU policies through the overview of recent EU health initiatives where scientific input is essential. The panelists particularly focused their presentations on EU cooperation on health technology assessment, the use of clinical real-world data to guide healthcare policies and the need for evaluation and regulation of artificial intelligence in medicine.

More information about the workshop as well as the speakers' presentations are available [here](#). The press release is available to read [here](#).

### 4. BioMed Alliance joins the TEHDAS Joint Action as a stakeholder



The BioMed Alliance has been selected to contribute as a stakeholder in the Joint Action Towards the European Health Data Space (TEHDAS). TEHDAS is a European Joint Action that started in February 2021 and funded by the Health Programme of the European Union. It is coordinated by the Finnish Innovation Fund SITRA and led by Member States to develop joint European principles for the secondary use of health data. The aim of the Joint Action is to guide the establishment of the European Health Data Space and earlier this year stakeholders were invited to apply to an open call, in order to get involved in the Joint Action and provide input and advice where necessary.

Several BioMed Alliance members suggested to apply jointly to the open call, and we have been selected as a stakeholder in three working groups of TEHDAS: the Stakeholder forum, the Work Package 5 "Sharing data for health", and the Work Package 7 "Connecting the dots". Through these work packages, BioMed Alliance and experts from our Policy Officers Committee will participate to the work of the Joint Action by providing expertise and information to guide the development of the new EHDS. We will share more information with you as the work of the Joint Action progresses.

More information on the TEHDAS Joint Action is available [here](#).

### 5. Don't miss your chance to register for the Spring Meeting



The 2021 online BioMed Alliance Spring meeting is only a few weeks away and the programme is packed with a number of internal and external speakers. Do not forget to register your participation as soon as possible to secure your spot.

We will start the morning session on 20 May at 10.30 sharp with a discussion on BioMed Alliance activities. The activities of our Taskforces, WGs and Committees will be discussed, and you will be asked to vote on our revised statutes and 2020 accounts. Please note that the morning session was extended by 30 minutes due to the large number of activities and will now end at 12.30.

In the afternoon we will continue at 15.00 with the policy session on the future of EU health data policy. We have invited three external speakers to share information on their work within the European Commission, on the Joint Action Towards the European Health Data Space (TEHDAS) and the Code of Conduct for Health Research. Then we will listen to two presentations from BioMed Alliance members from EAU and ESPR on the Pioneer project and e-Newborn benchmarking

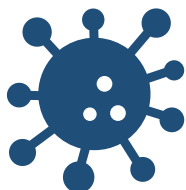


## Biomedical Alliance in Europe

programme. Afterwards we will open up the floor to hear from you regarding any experiences or questions you would like to share. To prepare the discussions, we have launched a short survey on data sharing. Please fill it out [here](#) by 7 May.

The registration form is available [here](#), please fill it in by 14 May at the latest. Because the event takes place online, we have space to accommodate more participants so feel free to forward the invitation within your organisation. For more information, please see the agenda [here](#).

### 6. BioMed Alliance joins the call for an extended mandate of the ECDC



The BioMed Alliance joined the European Chronic Disease Alliance (ECDA) and 9 other European health stakeholders in signing a joint letter to the Council of the European Union calling for an extended mandate of the European Centre for Disease Prevention and Control (ECDC).

The joint letter highlights the need for an integrated public health approach where the scope of the ECDC is expanded to other health issues than solely communicable diseases. Indeed, the letter emphasises the clinical links between communicable diseases and non-communicable diseases and the need to address non-communicable diseases when considering the actions to prevent and control infectious diseases. The letter also argues that enhancing the data collection-efforts could provide important health benefits and foster health promotion. The full letter is available for reading [here](#).

### 7. Upcoming

- The **IVD Working Group** will hold its next meeting on 18 May from 9.30-11.00
- The next meeting of the **Policy Officers Committee** will take place on 26 May.
- The **Spring Meeting** will take place online on 20 May. Please note that the timeslot of the **Morning Session** BioMed Alliance Activities was extended and will now take place from 10.00-12.30 CEST. The Afternoon Session on EU Health Data Sharing will take place from 15.00-17.00.
- The **General Assembly** will be organised on 30 November. Depending on the situation of 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



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 21<sup>st</sup> of each month. Thank you for your submissions!

### European Cancer Organisation: publishes its Annual Report “2020 in Review”



The European Cancer Organisation (E.C.O.) recently published its Annual Report “2020 in Review” detailing the policy work of the organisation and its key outputs and advocacy successes for the past year.

Cancer prevention and care, as any other life-threatening disease and the medical sector in general, were highly impacted by the COVID-19 pandemic slowing down prevention, diagnosis, treatments, and recovery care. The pandemic also greatly impacted the work and functioning of medical societies, the organisation of congresses and the way they advocate for better and stronger healthcare policies. This is why it is important to acknowledge that despite the difficult past year our member societies were determined to keep carrying on their work and not be stopped by the external events of 2020. In the 2020 Annual Report of the European Cancer Organisation, we are pleased to see the successful implementation of the four-year Strategy that includes developing further their oncopolicy and advocacy work at the European level, the establishment of nine Focused Topic Networks to facilitate joint projects and consensus building, as well as the launch of their new brand and website.

With the new EU4Health programme establishing the EU Cancer Mission and the recent launch of the Beating Cancer Plan, ground-breaking work and initiatives on cancer policy are being put in place at the European level.

For more information, the Annual Report of E.C.O. is available [here](#).



## Biomedical Alliance in Europe

### EANM: 34<sup>th</sup> Annual Congress of the European Association of Nuclear Medicine



The European Association of Nuclear Medicine (EANM) announced the date of its 34<sup>th</sup> Annual Congress that will take place virtually on 20-23 October 2021, unless the Corona situation allows the organisation of a hybrid event (online and face-to-face combined). The pre-Congress Symposia will take place on 4-6 and 11-13 October 2021. The programme of the Congress is very complete with plenary sessions, a Joint Symposia reflecting on the multidisciplinary of nuclear medicine, as well as sessions focussing on Continuing Medical Education.

The preliminary programme and registration form are available [here](#).