

Biomedical Alliance in Europe

# UPDATE JULY

2021

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## 1. Prof. Macintyre urged for more investment in digital training and skills of healthcare professionals at French parliament



Thanks to the BioMed Alliance efforts to engage and collaborate with [EIT Health](#), Professor Elizabeth Macintyre, member of the BioMed Alliance Board of Directors and chair of the IVD Working Group, spoke at the Assemblée nationale in Paris on July 7. Prof. Macintyre attended a workshop focusing on digital health skills and tools. The workshop co-organised by EIT Health and the Assemblée nationale is part of the programme “Digital & Health for all: what action needs to be taken for tomorrow’s public health?” targeting French legislators and policymakers with the aim to explore how the health workforce can be equipped adequately for the rapid digitalisation of health research and health care.

During the session, Professor Macintyre emphasised the importance of educating health care professionals (HCPs) on the digital and regulatory aspects of their work, especially as the science, the profession and the regulatory landscape are evolving rapidly. A wrap-up session presenting the conclusions and best ideas that emerged from all the thematic workshops of the programme took place on Tuesday 13 July. The recording of the conference will be available in French on the website of AI for Health [here](#).



## 2. Regulatory Affairs and Medical Devices Taskforce updates its structure



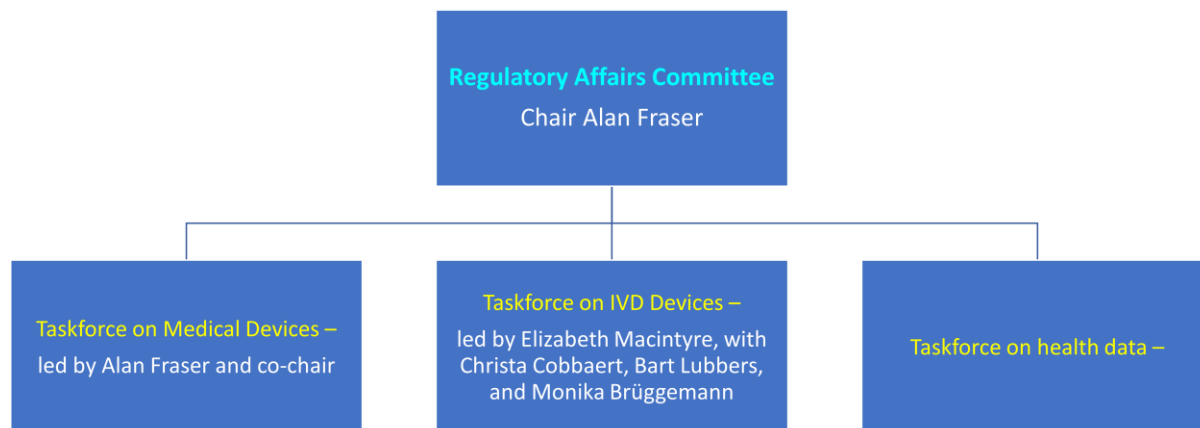
The advocacy activities of BioMed Alliance are growing, and we are tackling an increasing number of diverse regulatory issues within our taskforces as we are becoming more and more active on the European advocacy stage. It was needed to restructure the Regulatory Affairs and Medical Devices Taskforce, which is becoming the Regulatory Affairs

Committee. The restructuring will allow us to streamline our communication effort and to strengthen our advocacy power to influence and inform on regulatory affairs. We also want to make sure our members are involved in these communication and advocacy efforts in the most pertinent way; the new structure will allow us to ensure they are participating to targeted discussions depending on the issues at stake and their area of expertise.



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The new Regulatory Affairs Committee is formed of three sub-groups: the Taskforce on Medical Devices, the Taskforce on IVD and the Taskforce on Health Data. Gathering each topic under the pertinent Taskforce overseen by one main Committee will allow us to advocate more efficiently on the ongoing EU health initiatives and the related regulatory issues.



- **Health Data**

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. For instance, the European Commission has recently announced plans for Europe's digital transformation by 2030, '[Europe's Digital Decade](#)' and launched a series of initiatives relevant for the health sector including the proposal for the Artificial Intelligence Act, the Data Governance Act and plans for the European Health Data Space.

After discussions in our Policy Officers Committee, BioMed Alliance was recently accepted as a registered stakeholder in the Joint Action Towards the European Health Data Space (TEHDAS). The new Taskforce on Health Data gathering experts with experience in health data sharing had its first meeting on 8 July. This taskforce intends to combine expertise 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 European Health Data Space and other relevant EU health data initiatives.

The meeting was the occasion to present the taskforce and its purpose to the experts, but also our participation to the TEHDAS Joint Action and how we can efficiently contribute to the Joint Action. The experts also provided input on the latest public consultation of the European Commission on the European Health Data Space (EHDS) to which we submitted a BioMed Alliance response. On this occasion we also released a statement highlighting the main concerns we expressed in the public consultation, which is available to read [here](#).

- **Artificial Intelligence**

Artificial Intelligence is also an important topic high on the EU agenda with the publication of a [proposal for a Regulation laying down harmonised rules on artificial intelligence](#), the Artificial Intelligence Act (AIA), by the Commission last April. The proposal is currently being discussed in

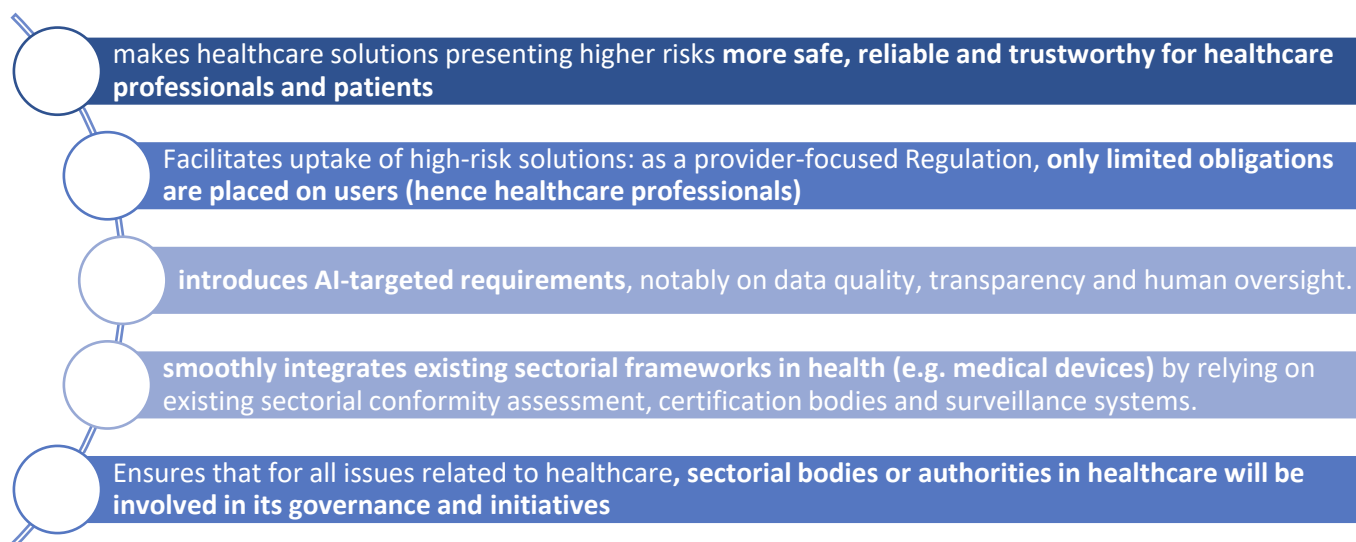


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Parliament. During the last meeting of the Regulatory Affairs Taskforce on 13 July, we had the opportunity to listen to Salvatore Scalzo, expert from the European Commission, who presented the draft Regulation and its application to the health field to the Taskforce members. The Commission's general approach to AI is that it is an extremely important and useful technology for the society in general, but it also creates certain risks for consumers' safety and for fundamental rights. Therefore, the new regulation takes a risk-based approach, minimising risks on the one hand while facilitating uptake and trust among the users, and especially when it comes to the trust within healthcare systems and among professionals.

The Artificial Intelligence Act is designed as a horizontal regulation, applicable across different sectors and integrating many existing sectorial regulations, including healthcare related legislations such as the Medical Devices Regulation. According to its risk-based approach, the regulation sets up a series of escalating obligations depending on the class-risk of the Artificial Intelligence systems, going from minimal risk to unacceptable risk, which are prohibited.

- **In a nutshell, the proposed Regulation:**



### 3. Webinar: Maximising the impact of advocacy strategies



The BioMed Alliance will organise an internal webinar on how societies can measure the impact and effectiveness of their advocacy activities and strategies, after discussing this question within the Policy Officers Committee and seeing the interest of several members in knowing more about the development of advocacy activities. The webinar will

be the opportunity for policy officers and experts from every society to discuss and learn more about advocacy strategies, how to measure their effectiveness and how it is possible to maximise their impact.

The webinar will take place online on **22 September from 10.30-12.00 CEST**, anyone who is interested is more than welcome to attend the meeting. We will also have the chance to hear more about the practical advocacy experience and work of three of our policy experts; Sarah Collen from EAU, Christina Dimopoulou from ESC and Jacqueline Bowman from EASO. They will each speak about their own experience and approach to create, implement, and assess advocacy strategies within their organisation. They will share their personal tips and advice on how societies can further develop their





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policy activities and maximise their impact on the European policy stage. We will soon communicate more information as well as the link to a registration form so everyone can register for the webinar.

### 4. New survey on the current use of IVD tests in diagnostic laboratories



The application date of the new EU Regulation on In Vitro Diagnostics (IVDR) is set for 26 May 2022 and comes with substantial regulatory changes. This will have important consequences for diagnostic laboratories, for example for the use of laboratory developed tests which play a key role where no suitable alternatives are available on the market. The BioMed Alliance IVD WG has been discussing the IVDR implementation and raised awareness on the consequences for the diagnostic sector.

The European Haematology Association Task Force on IVD in collaboration with the BioMed Alliance Task Force on IVD and with expertise from Prof. Christa Cobbaert from the European Federation of Clinical Chemistry and Laboratory Medicine, created a questionnaire on the current use of different IVD tests in diagnostic laboratories. The objective of the questionnaire is to gain insight into the current situation for medical laboratories, in particular the degree of (un)preparedness of medical laboratories for the IVDR implementation, and to make an accurate assessment of the potential impact that the IVDR will have on diagnostic laboratories and their test menu. BioMed Alliance members representing organisations active in the diagnostic sector are strongly encouraged to promote the survey, as any input provided will enable us to supply our members with relevant information and to better represent them in the implementation process.

We will keep you update on the results of the questionnaire, in the meantime, we need your help to disseminate this questionnaire as widely as possible. Please share it with the diagnostic laboratories in your network. We implemented the questionnaire under two different formats to accommodate people to the best: as a Word document and an online version on Surveyrock. You are welcome to complete the version that you prefer.

You may find the Word version of the question [here](#), and the online survey [here](#).

### 5. EU4Health 2021 Work Programme: 1<sup>st</sup> calls released



In our June Update we informed you that the European Commission had published the Work Programmes for Horizon Europe, including the EU4Health 2021 Work Programme. The EU4Health is the next health programme and the EU's ambitious response to COVID-19 aiming to address healthcare systems' resilience beyond crisis response only. The first EU4Health calls for 2021 have now been published as well, and will open on 29 July on the Commission's [Funding and Tenders Portal](#) until 15 September (the closing date for applications).

The published calls encompass:

- Action grants on substances of human origin (SoHo) - Increase resilience, ensure continuity of supply and access to safe and high-quality therapies, in particular in times of crisis
- Action grants for a project on the quality and safety of radiation technology in diagnosis and treatment of cancer



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- Action grants on collection tasks in relation to updating the European Cancer Information System to monitor and assess cancer screening programmes
- Action grants for inter-speciality cancer training programme
- Action grants for the EU Network of Youth Cancer Survivors

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

Furthermore, if you want to help the European Commission to develop further the EU4Health programme and shape the priorities and strategic orientations for the future EU4Health annual Work Programmes, you have the opportunity to do so by replying to the last Stakeholders consultation launched by the Commission to gather input and thoughts from stakeholders on the 2022 EU4Health annual Work Programme. The survey is open until 28 august [here](#).

## 6. Upcoming

- The **internal webinar on maximising the impact of advocacy strategies** will take place on 22 September from 10.30-12.00.
- 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.





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## 7. 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!

### EBC: The Brain Innovation Days – United for Brain Innovation



The European Brain Council (EBC) is organising the Brain Innovation Days on 12-13 October 2021 in Brussels, Belgium, as an in-person event. The event will focus on the theme of innovation in the brain field and will bring together opinion leaders and stakeholders from the ever-growing brain innovation ecosystem to create synergies and showcase the importance of brain innovation. The event will take place over two days filled with policy-driven sessions, application-led breakout sessions and Agoras, an exhibition and showcase space, matchmaking/networking activities and inspiring Brain Talks.

Innovation in healthcare is a major element to develop new and improved health policies and health related technologies that will enhance our health systems as well as citizens' health and safety of care. Such event, focusing on innovation in a medical field, is a great opportunity to connect innovators with funders, researchers with start-ups and innovation partners, and policymakers with the health & research communities.

For more information, please visit the Brain Innovation Days [website](#).

### E.C.O.: 2021 European Cancer Summit



The European Cancer Organisation (E.C.O.) is organising the [European Cancer Summit 2021](#) on 17 and 18 November 2021, both virtually and as an in-person event in Brussels. Every year, E.C.O. brings together leading oncology experts, experienced patient advocates, key opinion leaders, policy makers and politicians to discuss key issues in reducing the burden of cancer, saving, and improving the lives of patients and the public.



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This year, the summit will focus on the implementation of Europe's Beating Cancer Plan and the EU Cancer Mission's recommendations, including through the nine European Cancer Organisation's [Focused Topic Networks](#), representing key areas for improvement in cancer policy. The panel is still in progress but already promises interesting discussions on on-going health related initiatives and policies with the list of confirmed speakers announcing among others; Stella Kyriakides, EU Commissioner for Health and Food Safety, alongside a number of MEPs, including Véronique Trillet-Lenoir, Manfred Weber, Sara Cerdas, Nicolae Stefanuta, Frances Fitzgerald and Alessandra Moretti.

The preliminary programme of the event is available [here](#). Please note that registration is mandatory to attend the event, and the European Cancer Organisation is offering reduced registration fees for any registration before 17 September 2017. More information on the summit and on the registration is available [here](#).

