



Biomedical Alliance in Europe

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1. Implementation IVDR: a ticking time bomb for the diagnostic sector?



Laboratory experts from the BioMed Alliance IVD Working Group released a new statement highlighting a looming threat for the diagnostic sector, the slow implementation of the new In Vitro Diagnostic Regulation (IVDR). They argue that urgent actions are necessary now to prevent a collapse of the diagnostic sector.

The application date of the new In Vitro Diagnostics Regulation is only one year away (26 May 2022) and there are widespread concerns that the implementation is not progressing quickly enough. To date, many critical regulatory elements are not in place and important guidance is still lacking, making it extremely difficult for the EU diagnostic sector to be fully prepared in time for May 2022. The new regulation proposes stricter safeguards for tests and additional elements in the regulatory framework for IVD tests. Under the new system, it is e.g. expected that 90% of tests will need assessment by Notified Bodies for the first time, but only 4 Notified Bodies have been appointed so far.

With the majority of medical decisions made on the basis of diagnostic tests, serious consequences for the European healthcare system and patient care could follow. The BioMed Alliance has provided an overview of the implementation process and the steps to take and hopes that the issue will feature high on the EU agenda so pressing issues can be addressed.

Read more [here](#).

2. Spring Meeting 2021 stirred new discussions on BioMed Alliance activities



Even though spring weather was still on hold in Brussels, the annual BioMed Alliance Spring Meeting took place on 20 May. The meeting was held online due to the COVID-19 pandemic. This year there were two separate well-attended sessions, one in the morning on our activities and one in the afternoon on EU health data sharing.

In the morning we listened to a series of presentations from our taskforce and working group chairs on recent BioMed Alliance activities and next steps. Afterwards, we proceeded with an overview of the accounts which were unanimously approved by BioMed Alliance members. There was also a discussion on the revision of the statutes, but the vote on the changes was postponed as members proposed to finetune the definition of Europe.

During the afternoon session we looked into developments at EU level in the field of health data sharing. Health and health data sharing are currently high on the EU agenda, with initiatives like the European Health Data Space and discussions on the application of the General Data Protection Regulation in relation to health data sharing. We were joined by Markus Kalliola who presented the Joint Action Towards the European Health Data Space (where BioMed Alliance participates as a stakeholder) and Dr. Michaela Mayrhofer who provided more information on the BBMRI-ERIC code of conduct for health research. We then continued the session with short presentations from Prof. Neena Modi on the e-Newborn benchmarking project, Prof. James N'Dow on the Pioneer project and Prof. Per Kjaersgaard-Andersen on the CORE-MD project. We ended the session with an open discussion on the future of EU health data sharing, and how medical societies can contribute to future discussions.



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The office is currently preparing the minutes and will send them to you along with the presentations in due time.

3. Where we are now: Recap of our activities in 2021



The year 2021 is only just getting started but it has already been an eventful couple of months. The BioMed Alliance office has prepared a short leaflet providing an overview of our activities so far this year. Take a look at the main highlights that we have achieved thanks to your contributions, and let us know if there is anything you would like to be

involved in! You can find the leaflet [here](#).

4. BioMed Alliance contributes to discussion on health data sharing



Health Data Sharing is a key issue at EU level and the European Commission has introduced a range of new initiatives like the European Health Data Space, the 1 million genomes project and the Artificial Intelligence strategy that aim to facilitate European coordination and cooperation. Member states are also contributing to this work, for example within the Joint Action Towards the European Health Data Space (TEHDAS), which focusses e.g. on governance models and frameworks for the European Health Data Space.

Due to the importance of this topic for clinical care and health research, the BioMed Alliance has contributed to the discussions to share the perspective of medical societies, healthcare professionals and researchers. We have e.g. contributed to the European Commission consultation on the European Health Data Space and are a stakeholder observer in WP 5 and WP7 of the TEHDAS Joint Action.

Survey on health data sharing

As part of this work, the BioMed Alliance conducted a survey ahead of the Spring Meeting to get an idea of your views and experiences in relation to health data sharing. In the survey, medical societies shared that:

- They consider the legislative framework including diverging GDPR implementation and interpretation to be one of the most important challenges in the collection, sharing and access to health data.
- They are concerned about issues around interoperability, ensuring data quality and safeguarding privacy and anonymisation.
- They perceive a lack of expertise, and a large majority highlighted that more guidance would be highly beneficial.
- More support for researchers, academics and medical societies and an exchange of best practices are needed.
- It is necessary to improve harmonisation and to find an appropriate balance between safeguarding privacy and promoting data availability, access and quality.
- Futures initiatives should address legal issues, develop an appropriate infrastructure for health data sharing, enhance data quality and access, ensure privacy and security without negatively impacting data sharing and building citizen trust in data sharing initiatives.



5. Registration for Research & Innovation Days 2021 open



The annual European Research and Innovation Days will take place on 23 and 24 June. Registration is still open, so register as soon as possible to secure your spot to be involved in exchanges on different research-related issues.

The Research and Innovation Days is the European Commission's Annual Flagship event, bringing together policy makers and researchers for sessions and workshops on the future of research policies. There are multiple health-specific sessions, and this year promises to be an important edition with the start of Horizon Europe and the ongoing COVID-19 Pandemic.

For more information, please find the programme [here](#) and the registration form [here](#).

6. Health related EU Public Consultations



The EU has actively been seeking stakeholder input in the development of health policies recently, resulting in an impressive number of public consultations. The BioMed Alliance has replied to many of them, including two consultations on the Health Emergency Response Authority (HERA), the first consultation on the European Health Data Space (EHDS) and others.

Several consultations are still open at the moment including:

- A [consultation](#) on rules for the new medical devices EUDAMED Database (DDL 22 June)
- A [consultation](#) on updated rules for orphan and paediatric medicinal products (DDL 30 July)
- A [consultation](#) on cross border healthcare and the evaluation of patient rights (DDL 27 July)
- A second European Commission [consultation](#) on the European Health Data Space (DDL 26 July)
 - BioMed Alliance will submit a joint response, please let us know if you have any input that you would like us to take into account.

7. Upcoming

- 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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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!

UEG: Ongoing actions to advocate and raise awareness on Digestive Health



UEG is pleased to announce the launch of the Digestive Health Group on June 15, 13:00-14:00. Together with MEP Tajani, former President of the European Parliament and Chair of the Digestive Health Group, UEG top experts will present the challenges and the way forward in tackling the burden of digestive diseases in Europe. Registration will open soon, more information [here](#). Interest groups are an excellent example of how interested MEPs can advocate for better policies in specific disease areas and closely cooperate with stakeholders.

The digestive health community is celebrating World Digestive Health Day on May 29. To mark the occasion, UEG carried out a public awareness campaign - **Digestive Health Month** - throughout May focused on the prevalence and impact of digestive health conditions. As this year's theme for **World Digestive Health Day** is "**Obesity: An Ongoing Pandemic**", UEG has launched a [virtual exhibition](#) where you can find a wealth of information, statistics and resources on the links between obesity and digestive health. You can also use #DigestiveHealthMonth on Twitter to follow the discussions.

UEG also wrote a [news article in UEG Journal](#) summarising the opportunities for Health within Horizon Europe, providing a nice overview of the different elements and particularly those relevant for Digestive Health Research.



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EAN: Virtual Congress about to kick off



BioMed Alliance President Wilfried Ellmeier will speak at the Scientific Theatre of the virtual congress of the European Academy of Neurology. Prof. Ellmeier will highlight BioMed Alliance activities and the longstanding cooperation with EAN on Monday 20 June.

The EAN will organise its 4-day virtual congress 2021 from 19 to 22 June. Participants will be able to attend a broad range of sessions to get the latest scientific information on a broad range of topics relevant to neurology.

More information is available [here](#).

European Cancer Organisation: call for urgent action as one million Cancer cases are undiagnosed in Europe due to COVID-19



Over one million Cancer cases in Europe are being missed due to Covid-19, according to [new data](#) published by the European Cancer Organisation (E.C.O). The findings, a stark reminder of the challenges facing cancer care services in Europe during the pandemic, coincide with the launch of [Time To Act](#), E.C.O's campaign to urge the public, cancer patients, policymakers and healthcare professionals to ensure Covid-19 does not continue to undermine the fight against Cancer.

The study, led by E.C.O, reveals that the Covid-19 pandemic has meant that:

- An estimated **one million Cancer cases could be undiagnosed** in Europe
- An estimated **100 million Cancer screening tests were not performed** in Europe during the pandemic, leading to later stage diagnoses and decreased overall survival
- **Up to 1 in 2 people with potential cancer symptoms** were not urgently referred for diagnosis
- **1 in every 5 cancer patients in Europe is currently still not receiving the surgical or chemotherapy treatment they need**

The data from this study and the [Time To Act](#) campaign tools, available in over 30 languages, were presented in a [virtual event](#) on 11 May 2021 with contributions from European political leaders including EU Health Commissioner Stella Kyriakides, MEPs from the European Parliament's Special Committee on Beating Cancer (BECA) and the Director General of DG SANTE, Sandra Gallina.

Dr Matti Aapro, E.C.O. President, said: *"The findings bring the impact of Covid-19 on Cancer into sharp focus. We desperately need urgent measures at the highest level of European policy to address the cancer backlog, restore confidence in cancer services and tackle workforce/supply shortages."*

Learn more about the campaign and get involved: www.TimeToActCancer.com



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EBC: Value of Treatment 2 Synthesis Meeting



The European Brain Council (EBC) is organising a Value of Treatment [Virtual Synthesis Meeting](#) on **8 June 2021 at 13:00-17:30**. The **Value of Treatment (VOT)** is a health economics and outcomes research project addressing all brain disorders, conceptualised in 2015 by EBC. The project's objective is to come up with recommendations to optimise patient care pathways and rationalise costs from a societal and

healthcare perspective.

Value Of Treatment is an important concept both in Health Economics and health policy making, the conclusions of the meeting may therefore also be relevant for other disease areas.

The **findings will be presented** during the meeting and discussions with policymakers, innovators, academia and industry, medical professionals and patient organisations will examine the most critical issues in brain diseases in Europe.