

Biomedical Alliance in Europe

UPDATE JUNE

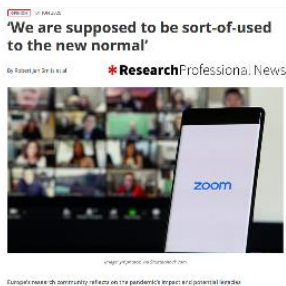
2020

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1. A unique opportunity to strengthen health research



The BioMed Alliance features alongside major players in the research field in an article by Research Professional News on the impact of the coronavirus pandemic on the research world.

In the article, President Wilfried Ellmeier and Senior Policy Officer Loredana Simulescu state that the COVID-19 pandemic demonstrated a need for more coordination and that there is a unique opportunity to build on the momentum and put in place mechanisms that address fragmentation in the European Health Research.

Read the article [here](#).

2. Regulating drugs, medical devices and IVDs during COVID-19 Pandemic



Prof. Elizabeth Macintyre (Chair of the IVD Working Group) and Prof. Alan Fraser (Chair of the Taskforce on Regulatory Affairs and Medical Devices) joined forces with ESC Colleagues to write an article on the regulation of drugs, medical devices and IVDs in relation to COVID-19. The article was published in the European Heart Journal on 18 June and analyses whether systems for the conduct of clinical trials and the evaluation of devices are able to respond to major health challenges.

Read the article [here](#).

3. IVD WG continues to work for better regulation



The BioMed Alliance In Vitro Diagnostics (IVD) Working Group held a teleconference on 26 June to discuss ongoing actions and the latest developments around the regulatory framework for IVDs. The group has been actively discussing the use of IVDs in the COVID-19 pandemic and the implementation of the new IVD Regulation with stakeholders and the European Commission under the lead of Working Group chair and Board Member Elizabeth Macintyre.

4. EU MFF: Negotiations on future budget carry on



As mentioned in [last month's edition of this newsletter](#), negotiations on the next Multiannual Financial Framework (MFF) and the recovery plan from the COVID-19 crisis are currently ongoing. The European Council met on 19 June to discuss the package of proposals that were presented in May, and they plan to hold an in-person meeting to continue negotiations in July. Negotiations are complex and the positions of countries differ greatly, and discussions behind the scenes will continue in parallel to the formal meetings over the coming weeks/months.

The proposals were modified after the COVID-19 pandemic and now contain a greater focus on research and health with a standalone health programme (EU4Health). While it is expected



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that the health elements will not be controversial, other elements such as the height of the budget and the details & funding of the recovery plan will most likely face more resistance.

The MFF is supposed to come into effect in 2021 but this timeline seems ambitious considering the complex negotiations ahead. It seems inevitable that the Commission's proposal will be amended or even delayed. If no agreement is reached by the beginning of next year, this could hinder the implementation of programmes like Horizon Europe and EU4Health. Nonetheless, considering the challenging circumstances it is more important than ever that the EU continues to have all necessary instruments at its disposal and that the proposals are adopted as soon as possible.

5. Survey on clinical trials & COVID-19



The Good Clinical Trials Collaborative has asked us to share a global survey to understand the impact of COVID-19 on running clinical trials.

Launched in June 2020, the Good Clinical Trials Collaborative, supported by grants from Wellcome, the Gates Foundation and the African Academy of Sciences, will review the principles of randomised clinical trials for all types of healthcare interventions, in all settings. It is led by Professor Martin Landray (University of Oxford & ESC).

Your feedback will contribute to the development of new guidelines that support a more efficient regulatory environment for clinical trials, allowing researchers to efficiently conduct the trials that are needed to improve patient care.

The survey will be open for 6 weeks, closing at 6pm (CEST) on Monday 20 July 2020. [Take the survey here.](#)

6. EU launches consultation on new pharmaceutical strategy



On 16 June, the European Commission launched an online public consultation on the [new Pharmaceutical Strategy for Europe](#).

The Pharmaceutical Strategy is intended to help ensure Europe's supply of safe and affordable medicines meet patients' needs and to strengthen the European pharmaceutical industry's position as an innovator and world leader. It is supposed to be future proof, reap the benefits of digitalisation, reduce the EU's dependency of imports from third-countries, tackle anti-microbial resistance and ensure the continued availability of medicines and vaccines (also in health crises and pandemics like COVID-19). The new strategy will inform the new EU health programme EU4Health and Horizon Europe.

The consultation is open until 15 September and available [here](#). In addition, the European Commission launched a survey on the roadmap which is open until 7 July and can be found [here](#).



7. BioMed members feature in HPP webinar series



On 22 June, the Thematic Network on “Profiling and training the health workers of the future” of the EU Health Policy Platform (EUHPP) organised a webinar on nurse education featuring a speaker from EULAR. The BioMed Alliance contributed to the proposal for this

network, and the webinar series highlights different aspects of education for healthcare professionals.

BioMed Alliance facilitated the participation of our members (EULAR and UEG) in the webinars organised in the context of the Thematic Network. EULAR participated in the webinar dedicated to the [Nurses' training and core competences: from digital skills to continuity of care and leadership skills](#). UEG is expected to contribute to the next webinar in the series on "Preparing Health Care Professionals for 'Future' Healthcare Challenges (AI and Robotics)"

8. Upcoming

- We are organising another call of the **Policy Officers Committee** on 1 July
- The second **EU Health Summit** will take place on 26 October 2020. This event is organised by the [EU Health Coalition](#), of which the BioMed Alliance is an active member.
- The **General Assembly** will be held on 26 November 2020