



Biomedical Alliance in Europe

UPDATE August 2019

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1. BioMed Alliance becomes recognised EMA Stakeholder



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The BioMed Alliance is now officially registered as an EMA Stakeholder. By registering as a stakeholder, the BioMed Alliance can easily be identified for consultation on relevant issues, will be kept up to date on events, receives communications and will be informed on EMA consultations.

A list of all eligible healthcare professionals organisations is available here: <https://www.ema.europa.eu/en/partners-networks/healthcare-professionals/eligible-healthcare-professionals-organisations>

2. New public private partnership unveiled to BioMed Alliance members

Next Public Private Partnership



BioMed Alliance organised a webinar together with EFPIA and COCIR to present the vision for the next public private partnership on health innovation and to discuss ways of involving the biomedical research community in the co-creation of the Strategic Research Agenda.

The next public private partnership for health, and successor to the Innovative Medicines Initiative (IMI 2), will bring together industry and the EU in a partnership that should foster health research and ensure that innovation will reach the patient in a timely manner. Unlike in the IMI, this new initiative will not just focus on pharmaceuticals but will also involve e.g. the medical devices, diagnostics, imaging, biotech and digital industries.

The Strategic Research Agenda has to be approved by the European Commission and included in the final legislative decision about future public private partnerships under Horizon Europe. The legislative proposal is expected to be finalised early next year and the proposed initiative will start 2021. In the meantime, BioMed Alliance continues the dialogue with the industry to examine ways of providing consistent input to the Strategic Research Agenda. A concrete outcome of the webinar was to organise a series of joint meetings with BioMed Alliance experts. The goal of the meetings is to dive into aspects of the agenda and propose concrete solutions for topics that are important to BioMed Alliance members such as: big data, clinical studies, education and research sustainability.



3. Joint workshop on navigation EU health research funding



On 19 November the BioMed Alliance and the European Association of Urology are organising a workshop on Horizon Europe and the EU research funding landscape in Europe. The workshop entitled '*Navigating EU health research funding. Looking ahead to Horizon Europe 2021-2027*' will take place the day before the General Assembly from 14.00-18.00 at Rue de l'Industrie 24 in Brussels.

Horizon Europe is the EU's research and innovation framework programme for the period between 2021-2027. The workshop will take an in-depth look at funding opportunities within the new framework programme, particularly for biomedical and health research. The event is divided into four parts: an introduction, an overview of EU funding opportunities for health research, a panel discussion on strategic approaches and an exchange on tips for success

Participation is open, anyone with an interest in research is encouraged to register by e-mail to: office@biomedeuropa.org

4. Open consultation on Horizon Europe:



The open consultation on the [Horizon Europe Strategic Plan](#) is open until 8 September and the BioMed Alliance will respond.

We welcome the Plan as it stands and acknowledge the underlying challenges that must be tackled in order to ensure citizens are healthier, wealthier and live in a fair, climate-neutral, green and inclusive Europe. The BioMed Alliance commends the European Commission's work and we welcome the strong emphasis on better coordination of health research and cross-fertilisation and collaboration across the Horizon Europe's pillars and clusters. We are happy to see that [the BioMed Alliance strategic recommendations](#) are outlined in the upcoming framework programme. The open consultation seems to be just a formality, but we will respond to it by emphasising the need for health research sustainability and for longer-term collaborative initiatives.

In addition, we plan to send out a statement with our partners from the EU Health Coalition calling for a right balance between health research and innovation throughout Horizon Europe and cross-fertilisation and coordination across all relevant disciplines and the framework programme's pillars.



5. BioMed Alliance invited to advise EC during workshop on novelty



The Joint Research Centre (JRC) of the European Commission has asked the BioMed Alliance to identify experts in specific disciplines to advise on novelty in the context of medical devices. Experts have been identified by the Taskforce on Regulatory Affairs and Medical Devices and they will take part in a JRC workshop in October. This workshop will be attended by different stakeholders including Member States, notified bodies, industry and clinical experts.

The Commission intends to develop a guidance document for experts on the consistent interpretation on decision criteria including novelty, in the context of the new expert panels on medical devices.

6. Upcoming

- In the coming months (exact date not known), the European Commission will launch a call for experts to take part in the new **EU Medical Device Regulation expert panels**. These experts will play an important role in the evaluation process of high-risk medical devices.
- PARADIGM, PFMD and EUPATI are organising a **patient engagement open forum** in Brussels on 18 and 19 September. The two-day programme features a number of sessions exploring the different aspects of patient engagement.
- The next meeting of the **CME Experts Permanent Committee** will take place on 26 September in our office (Square de Meeus, 29, Brussels).
- On 7 November, the BioMed Alliance and the Berlin Institute for Health organise an **event on translational research** in Berlin as part of the Berlin Science Week. The event will include a panel discussion with key speakers exploring different aspects related to the value of translational research.
- The first meeting of the **In Vitro Diagnostics working group** will take place on 12 November in our office.
- The **European Patients Forum Congress** will take place from 12-14 November in Brussels. BioMed Alliance Executive Director Michel Ballieu will participate as a panellist in the session on the role of patients in professional education on 14 November.
- We will organise a **workshop on Horizon Europe** (the EUs next Research and Innovation Framework Programme) with the EAU on 19 November from 14.00-18.00 in Brussels. More information will follow, please confirm your attendance to: office@biomedeuropa.org
- The BioMed Alliance **General Assembly 2019** takes place on 20 November from 10.00-16.00.