Biomedical Alliance in Europe

Minutes of the Spring Meeting

14 May 2019
Square de Meeûs, 29 - Brussels (2nd floor)
10.00-16.30

Participants:

Organisation	Name	Position
Speakers		
Interel	Richard Steel	Head of Parliamentary Intelligence Unit
European Commission	Jean-Claude Burgelman	Head of Unit B2, Open Science
Wellcome Trust	Robert Kiley	Head of Open Science
FEBS	Laszlo Fesus	Chair, FEBS Publications Committee
ESC	Valentina Tursini	Scientific Publications Director
ESC	Thomas F. Lüscher	Editor in Chief of the European Heart Journal
ESC	Alan Fraser	Chair of the taskforce on regulatory affairs and medical devices
EAN	David Vodušek	Chair of the CME Experts Committee
ESC	Piotr Szymański	Member of the ESC Regulatory Affairs Committee
BioMed Alliance Members		
BioMed Alliance	Axel Pries	President
	Wilfried Ellmeier	President-Elect
	Colm O'Morain	Past-President
	Gunhild Waldemar	Treasurer
	Berthold Koletzko	Member of the Board of Directors
	Tobias Welte	Member of the Board of Directors
	Elizabeth Macintyre	Member of the Board of Directors
	Steffen Gay	Member of the Board of Directors
	Chantal Mathieu	Member of the Board of Directors
	Michel Ballieu	Executive Director
	Loredana Simulescu	Senior Policy Officer
	Marieke Meijer	Communications & Project Officer
EAACI	Nazli Uysal	Delegate
EACTS	Hendrik Jan Ankersmit	Delegate
EAN	Timea Varga	Delegate
EANM	Wim Oyen	President
EASD	Lena Wedeken	Scientific Officer
EASL	Margaret Walker	EU Public Affairs Consultant
	Thomas Berg	Vice-secretary
	Joël Walicki	Editorial Manager Journal of Hepatology/JHEP Reports

	Laurence Verhagen	Managing Director
EASO	Jacqueline Bowman-Busato	EU Policy Advisor
EAU	Sarah Collen	EU Policy Coordinator
EBC	Frederic Destrebecq	Executive Director
EFIS	Raivo Uibo	Delegate
EFORT	Adrian Ott	Chief Executive Officer
	David Limb	Delegate
EHA	Robin Doeswijk	Policy Officer
ERS	Matt Broadhead	Assistant publications manager
	Bill Werner	Executive Director
	Brian Ward	Director of Advocacy and European Affairs
ESA	Daniela Filipescu	Past President
	Marc Gheeraert	Executive Manager
ESC	Panos Vardas	Managing Chair of the European Heart Agency
	Isabel Bardinet	Chief Executive Officer
	Christina Dimopoulu	European Project Manager
	Stefania Santangelo	Advocacy and EU Project Officer
ESE	Vera Popovic	Delegate
	Dirk de Rijdt	Director of Commercial Services
ESHRE	Thomas Strowitzki	Delegate
ESICM	Joël Alexandre	CEO
	Guy Francois	Team Leader & Manager Research
ESMI	Doris Kracht	Executive Director
	Tony Lahoutte	Past-President
ESPGHAN	Raanan Shamir	President
ESPR	Pascal Fentsch	Senior Executive Assistant
EULAR	Johannes Bijlsma	President
	Federico Torres	EU Policy Officer
	Teresa Stadler	EU Policy Officer
FEBS	Emmanuel Fragkoulis	Chair of the Science and Society Committee
UEG	Mathilde Ollivier	Research Policy Manager
	Jana Tenglerova	EU Policy Advisor
External		
ERA-EDTA	Monica Fontana	Executive Manager
	Caroline Vinck	Editorial Manager Journal of Hepatology/JHEP Reports

Apologies:

- Jan Cools (EHA), editor-in-chief of the HemaSphere journal
- Prof Carmine Zoccali (ERA-EDTA) president
- ECTS
- EORTC

Biomedical Alliance in Europe

Morning session | the European Elections & Plan S

Introduction & Tour de Table

BioMed Alliance President Prof. Axel Pries welcomed all attendees and presented the outline of the meeting. See annex 1 for the full agenda.

European Elections

Richard Steel (Head of Parliamentary Intelligence Unit at Interel) shared his knowledge and predictions on the European Elections (see annex 2). He highlighted the process, key insights from the campaign, election forecasts and potential consequences.

Plan S

The second session focussed on Plan S, the open access plan initiated by Science Europe and research funding organisations and supported by the European Commission (see annex 3 for a briefing on Plan S). The session was moderated by Wilfried Ellmeier and Chantal Mathieu from the Board of Directors. They welcomed all participants and briefly introduced Plan S and the speakers.

To kick-start discussions, Robert Kiley, Interim Plan S coordinator from Wellcome Trust, provided a keynote speech highlighting the main elements of the plan and its consequences, particularly for medical societies (see annex 4). He argued that there are many misunderstandings regarding Plan S. The vision of Plan S is that all publicly funded research needs to be open accessible and reusable without delays. There are different routes to compliance: by publishing in open access journals, by publishing in hybrid journals under a transformative agreement, or in traditional journals if the manuscript is published in an open access repository. Robert Kiley also referred to the SPA-OPS project[1], which is supposed to provide learned societies with guidance on adapting to Plan S.

Afterwards, there was a panel discussion where Mr. Kiley was joined by Prof. Jean-Claude Burgelman (Head of Unit Open data Policies and Science Cloud, European Commission), Prof. Thomas Lüscher (editor in Chief of the European Heart Journal), Valentina Tursini (Scientific Publications Director, ESC) and Prof. Laszlo Fesus (Chair of the FEBS Publications Committee). Prof. Burgelman highlighted the European Commission's Open Access policy and the rationale behind it. He confirmed that there will be an obligation under Horizon Europe to publish Open Access.

Representatives of BioMed Alliance members generally support open access but have concerns about the content and implementation of Plan S. Panellists e.g. expressed concerns about the sustainability of open access journals for medical societies and argued that hybrid journals may be a better arrangement. As it stands, Plan S affects some actors more than others, big publishers may be able to adapt but for small societies this is more difficult. Panellists also worry that Plan S is too Europe centred, which may affect cooperation with e.g. the USA. At the same time, transformative agreements may lead to geographic inequality, as they are currently only focussed on the US and North-Europe but

[1] http://www.informationpower.co.uk/consultation/

not on Eastern-Europe or the Global South. In addition, open access removes one paywall but adds another, as the costs for publishing remain and still need to be covered. In general, they asked for more flexibility and more time regarding Plan S.

The session showed that there are still many concerns and confusion around Plan S and its implementation, and there is a need for continued discussions.

Afternoon Session | BioMed Alliance Internal Affairs

The afternoon session was dedicated to BioMed Alliance activities. Members were updated on ongoing activities and had the chance to provide input on both ongoing and upcoming activities.

Governance

The first item on the agenda for the afternoon session was a report by BioMed Alliance Treasurer Gunhild Waldemar on the accounts of 2018 (see annex 5 and 6). She asked members to vote to approve the accounts and a paper copy of the overview was also provided to attendees. The accounts were unanimously approved by the members of the General Assembly and they discharged the Board of Directors of their financial responsibilities for 2018.

Executive Director Michel Ballieu also welcomed three new members (EBC, EFFORT and ESICM) and stated that there are several potential new members in the pipeline. He asked all members to let him or the Board know if they know of any potential members that may be interested in joining the Alliance.

Update on ongoing activities

The second item was an update of all ongoing activities, including an example of advocacy activities and an overview of the activities of the taskforces and committee.

Axel Pries and Wilfried Ellmeier provided an update on BioMed Alliance advocacy activities on Horizon Europe which include promoting the increase of its budget and the establishment of the Steering Board for Health (see annex 7).

Secondly, CME Experts Permanent Committee chair Prof. David Vodušek presented the activities of this education Committee which include a cartoon, an article in the AJM and a survey which assesses members' CME accreditation activities (see annex 8).

Then, Prof. Alan Fraser outlined that the Taskforce on regulatory affairs and medical devices provided input to the European Commission on the new Medical Devices Regulation (see annex 9). Other important highlights were mentioned such as: Taskforce members' involvement in the European Commission Medical Devices Coordination Group, the creation of the In Vitro Diagnostics working group and the organisation of a workshop on Medical Device Registries on 17 June.

Afterwards, the chair of the Taskforce on clinical trials Prof. Colm O'Morain presented the activities of the taskforce which include the publication of an article in the European Respiratory Journal (see annex 10).

Future Directions

There are many possibilities for upcoming activities, and several of those were discussed in the third agenda item of the afternoon session.

Prof. Piotr Szymanski raised awareness on the European Commission proposal on joint Health Technology Assessment (see annex 11). He explained that researchers could be involved in horizon scanning and the different advisory groups on HTA but that this is currently often not the case. He also argued that joint HTA can have many benefits but that progress on the proposal is slow and that it may be worthwhile to come with a statement from the BioMed Alliance.

The BioMed Alliance will continue building and reinforcing relations with key stakeholders in the Brussels ecosystem. For example, Axel Pries explained that the European Commission has hinted that the BioMed Alliance may be asked to suggest potential topics for Horizon Europe. Members are asked to think about potential topics, and they may be consulted at a later stage. In addition, as the Steering Board for Health is not included in the final proposal for Horizon Europe, we could explore increased involvement in the next public-private partnership or establishing a shadow ‘Steering Board for Health’ with other stakeholders.

Prof. Berthold Koletzko, BioMed Alliance Board Member, also explained that the fragmented implementation of the General Data Protection Regulation continues to hinder cross-border health research (see annex 12). We have collected case studies and released a statement. In addition, we were asked by the European Commission to identify key questions that require further clarification.

President Axel Pries thanked all participants for coming. The meeting ended at 16.00.