



Biomedical Alliance in Europe

Ordinary & Extraordinary General Assembly
21st of November 2018

Minutes

List of participants

Organization	Name	Position
Alliance for Biomedical Research in Europe	Prof. Axel Pries	President
	Prof. Colm O'Morain	Past-President
	Prof. Françoise Meunier	Board member
	Prof. Wilfried Ellmeier	Treasurer
	Prof. Gunhild Waldemar	Board member
	Prof. Steffen Gay	Board member
	Prof. Welte Tobias	Board member
	Prof. Ulrich Jaeger	Board member
	Michel Ballieu	Executive Director
	Loredana Simulescu	Policy officer
European Academy for Allergy and Clinical Immunology	Bénédicte Faure	Delegate
European Association for the Study of Diabetes	Dr. Lena Wedeken	Delegate
European Academy of Neurology	Prof. Peter Van den Bergh	Delegate
	Eveline Sipido	Coordinator EU Affairs
European Hematology Association	Prof. Elizabeth Macintyre	EHA Delegate
	Robin Doeswijk	Project Coordinator European Affairs
European Society of Anaesthesiology	Prof. Daniela Filipescu	Delegate
	Marc Gheeraert	Executive Manager
European Society of Human Reproduction and Embryology	Prof. Thomas Strowitzki	Delegate
	Dr. Roy Farquharson	Chair
European Society of Cardiology	Prof. Alan Fraser	Delegate



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	Elisabetta Zanon	Advocacy Director
	Christina Dimopoulou	Project manager
European Respiratory Society	Brian Ward	Policy Director
	Werner Bill	CEO
Federation of European Biochemical Societies	Prof. Emmanouil Fragkoulis	Delegate
United European Gastroenterology	Prof. Julia Mayerle	Delegate
	Jana Tenglerova	EU Policy Advisor
	Doris Möstl	Executive Director
	Prof. Berthold Koletzko	Delegate
European Society for Paediatric Gastroenterology Hepatology and Nutrition	Prof. Gigi Veereman	Delegate
European Society for Molecular Imaging	Tony Lahoutte	Past president
The European League Against Rheumatism	Prof. J.W.J. Bijlsma	President of EULAR
	Federico Torres	EU Policy officer
European Association for the Study of the Liver	Prof. Tom Karlsen	Secretary-General
European Society of Endocrinology	Helen Gregson	Executive director
	Prof. Vera Popovic	Delegate
European Association of Nuclear Medicine	Dr. Kristoff Muylle	President
	Mr Henrik Silber	Executive Director
European Society for Paediatric Research	Pascal Fentsch	Delegate
European Association of Cardio-Thoracic Surgery	Kathy McGree	Executive Director
	Prof. Hendrik Jan Ankersmit	Delegate
European Calcified Tissue Society	Roberta Mugnai	Managing Director
European Federation of Immunological Societies	Prof. Raivo Uibo	Delegate
European College of Neuropsychopharmacology (ECNP)	Prof. Celso Arango	President
European Organisation for Research and Treatment of Cancer	Jean-Marie VLASSEMBROUCK	Delegate

Apologies:

European Atherosclerosis Society
 European Crohn's and Colitis Organisation
 European CanCer Organisation
 European Association of Urology
 European Society of Pathology
 European Forum for Research & Education in Allergy & Airway Diseases



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European Association for the Study of Obesity
Prof. Bernard Thorens: BioMed Alliance Board of Directors
Doris Kracht; Executive Director, European Society for Molecular Imaging

Governance

Validity

21-member associations were present or represented at the GA. At least two thirds (2/3) of the members (i.e. 20 out of 29 members) were thus present at the GA in accordance with the presence quorums stipulated in Articles 9.1 and 21.2 of the Articles of Association. Consequently, the meeting was validly constituted and therefore could validly deliberate and make decisions regarding the items on the agenda.

Budget 2018 & Dues:

The General Assembly resolved to approve the budget of the current financial year and the membership dues for the financial year 2019, on a proposal from the Board of Directors.

Votes: 21 yes

Budget 2019:

The General Assembly resolved to approve the provisional budget for the financial year 2019. (Please see annex 1)

Votes: 21 yes

Resignation:

The General Assembly acknowledged the resignation of European CanCer Organisation (ECCO), and of European Crohn's and Colitis Organisation (ECCO-IBD) as Members of the Association. According to Article 6.4 of the Articles of Association, the resignation of both organisations shall become effective as of January 1st, 2019.

Board of Directors size:

The General Assembly, according to Article 11.1, paragraph 4 of the Articles of Association, resolved that in addition to the three (3) Board members being representatives of the Founding Members, six (6) additional shall be elected as Board members.

Votes: 14 yes & 7 n

President:

The General Assembly, according to Article 12.2 of the Articles of Association, acknowledged that Prof. Axel Pries aforementioned, after having served one year as President-Elect, has automatically become President of the Board as of January 1st, 2018. His mandate as President will expire on December 31, 2019.



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The General Assembly, according to Article 12.2 of the Articles of Association, acknowledged that Prof. Axel Pries will serve as a Board member until the end of his mandate of President.

President-Elect:

The General Assembly resolved, according to article 12.2 of the Articles of Association, to elect Prof. Wilfried Ellmeier as new President-Elect with effect on January 1st, 2019. His mandate will expire on December 31, 2019.

Votes: 21 yes

End of Mandate:

The General Assembly acknowledged the end of the mandate of the following Board members:

- Prof. Caroline Dive,
- Prof. Jean-Paul Sculier,
- Prof. Françoise Meunier,
- Prof. Ulrich Jaeger,
- Prof. Bernard Thorens,

Re-election:

The General Assembly resolved, according to Articles 11.1 and 13 of the Articles of Association, to re-elect Prof. Gunhild Waldemar. Her mandate will expire on December 31, 2021.

Votes: 20 yes, 1 no

Elections:

a) The General Assembly resolved, according to Articles 11.1 and 13 of the Articles of Association, to elect Prof Elisabeth Macintyre. Her mandate will expire on December 31, 2021.

Votes: 16 yes

b) The General Assembly resolved, according to Articles 11.1 and 13 of the Articles of Association, to elect Prof. Berthold Koletsko. His mandate will expire on December 31, 2021.

Votes: 12 yes

Nomination:

The General Assembly, according to Articles 11.1 and 13 of the Articles of Association, acknowledged the designation as Board member of Prof. Chantal Mathieu, representative of EASD, with effect on January 1st, 2019. Her mandate will expire on December 31, 2021.

Registered Office:

The General Assembly resolved to transfer the registered office from Avenue E. Mounier 83, 1200 Brussels to Square de Meeûs 29, 1000 Brussels with effect immediately after the General Assembly of November 21, 2018.

Votes: 21 yes



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Statutes:

The General Assembly resolved to replace in Article 1 of the Articles of Association as follows:

“Article 1 Name”

An Association has been established pursuant to Title I of the Belgian law of 27 June 1921, as amended, for a not-for-profit purpose under the name of “Biomedical Alliance in Europe”, abbreviated as “BioMed Alliance” (hereafter the “Association”). The full or abbreviated names of the Association may be used separately and the Association shall be commonly referred to as “BioMed Alliance”. English shall be the working language of the Association.”

Votes: 21 yes

The General Assembly resolved to replace in Article 2 of the Articles of Association the words “Avenue E. Mounier 83, 1200 Brussels” by “Square de Meeûs 29, 1000 Brussels”.

Votes: 21 yes

The General Assembly resolved to replace Article 3 of the Articles of Associations as follows:

“Article 3 Goals and Objectives”

The Association’s goals and objectives are exclusively devoid of any for-profit motives. The Association’s principal goals and objectives are to promote the best interests and values of researchers and healthcare professionals organised in not-for-profit scientific medical associations and organisations, across all medical disciplines in Europe, in those general areas where common interest is identified.

The Association shall also aim to speak as a common voice of all its members in seeking to:

- facilitate and improve biomedical research in Europe;
- develop a framework for better training and mobility of researchers and healthcare professionals in Europe;
- represent its members being medical associations, and their members, in common policy and strategic matters; and
- improve public understanding of medical science in Europe.

The Association intends through its actions to:

- promote excellence in European biomedical research;
- strengthen the representation of biomedical researchers, disciplines and associations;
- advocate for increased funding in favour of biomedical research; and
- thereby improve the health and well-being of all citizens of Europe.

The Association may use all means that contribute directly or indirectly to the realisation of these goals and objectives, as they may be interpreted in the broadest sense. The Association may exercise the right of ownership or possession of office premises, property, and assets, both liquid and immovable, and shall use them for the exclusive purpose of advancing the Association’s goals and objectives, as established in these Articles of Association. The Association may also hire personnel, conclude legal agreements, collect funds, in short, exercise all powers or have them exercised, provided that they are in furtherance of its goals and objectives.



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In pursuit of these goals and objectives, the Association may conduct, operate, coordinate, participate in, and support charitable and other publicly beneficial programs and activities, whether they are programs and activities of the Association or of other physical persons and/or legal entities, that the Board of Directors may, in its sole discretion, deem constructive and appropriate.

The Association may carry on such business or other activities as are incidental to the foregoing purposes and further the goals and objectives of the Association;

The Association may conduct any other activities that may be necessary, useful or desirable for the furtherance or accomplishment of these goals and objectives, provided that those activities would not endanger the Association's income tax exempt status.

The activities of the Association will be carried on without purpose of seeking a material gain for its members and any income, profits or other accretions to the Association will be used in promoting the goals and objectives of the Association.

The Association's activities are expected to complement and supplement the activities of its members. Each member reserves the right to carry on its own activities in its own areas of medical interest and expertise".

The General Assembly resolved that the amendments of Articles 1, 2 and 3 of the Articles of Association will enter into force immediately after the General Assembly of November 21, 2018.

Votes: 20 yes 1 no (four fifth of presents: 17)

Internal Rules:

The General Assembly approved the amendments and additions to the Internal Rules proposed by the Board of Directors and resolved that these will enter into force immediately after the General Assembly of November 21, 2018 (please see annex 2).

Votes:

Page 2: 21 yes

Page 4: 20 yes & 1 no

Page 6: 21 yes

Page 11: 18 yes & 3 no

Page 12: 21 yes

Proxy:

The General Assembly resolved to grant a special power of attorney to Mr. Antoine DRUETZ, Ms. Alix DEGREGZ, Ms. Charlotte FUMIERE and Ms. Sakine YILMAZ, in their capacity of lawyers, with their office located at 1170 Brussels, Chaussée de la Hulpe 166, and to Mr. Koen De Muylder, with his offices at 1000 Brussels, Quai de Willebroeck 37, with power to act alone and the right of substitution, to do all that is necessary or useful to fulfil the required administrative and publication formalities and to perform all actions generally required regarding the abovementioned resolutions, including, but not limited to, the modification of the registration of the Association with the Crossroads Bank for Enterprises, the modification of the registration of the Association with the VAT authorities, drafting and filing of the



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coordinated version of the Articles of Association with the clerk's office of the Commercial Court of Brussels, proceed with any publication in the Annexes to the Belgian Official Gazette (including the drafting, filing and signature of any publication form).

Votes: 21 yes

Activities

BioMed Alliance role in the EU health arena

EU Health Summit

The BioMed Alliance teamed up with other European Organisations to hold a EU Health Summit on 29 November 2018 in Brussels. We were leading one of the 4 working groups on Research and Innovation. The BioMed Alliance along with the partner organisations put together recommendations for a shared vision for the future of health in Europe, calling upon the next European Commission and European Parliament to bring about necessary changes. The working group on Research and Innovation has proposed 4 main recommendations to foster health research in Europe. More info can be found on the BioMed Alliance website.

Horizon Europe and the Steering Board for Health

The next framework program Horizon Europe was discussed in the European Parliament, by the ITRE committee (Industry, Research and Energy). We worked closely with the leading members of the EP and advocated for the establishment of a "Steering Board for Health (SBH)". The ITRE committee voted the legislation, including the introduction of a SBH on November 21.

The proposed science-led SBH, composed of stakeholders from biomedical research and innovation, other relevant sectors of research and industry and with strong participation of patient representatives and citizens, could be of specific value for coordinating health programs and health missions under Horizon Europe. For more information, please visit our website. In order to ensure that the Steering Board for Health will survive during the triologue negotiations, sustained communications and advocacy efforts should be implementing in the coming months especially targeting the Council of the European Union.

Investigator Independent clinical trials

The White Paper "Moving forward from drug-centered to patient-centered research" was published this year and communications efforts to promote the paper have been implemented. The BioMed Alliance White Paper has been promoted through our members channels (EULAR newsletter and website, FEBS communications platform and EAN newsletter and website).

An article presenting the core messages of the BioMed Alliance White paper was published on Research Europe (<https://www.researchresearch.com/news/article/?articleId=1377640>) and to the European Respiratory Journal. The manuscript submitted to the European Respiratory Journal was reviewed by esteemed editors and an improved version would be submitted in due course.



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The TF's members should meet after the event organised by EORTC in collaboration with STOA to define policy objectives and to identify the next steps. The STOA event will take place on January 10th, in the European Parliament.

The future of CME

22 members societies joined this Task Force, which was created in April 2017, to work on possible actions in order to protect our members societies' business model against the threat resulting from the industry intention to develop their own medical education activities.

An interesting and efficient mix of leaders and of senior staff attended the 6 meetings organised so far, they concluded to develop awareness towards HCPs and lay public pointing out the importance of unbiased scientific content.

An article has been produced, endorsed by all 22 societies, and about to be published in a scientific journal, as well as a cartoon targeting the lay public.

Regular contacts with EFPIA and MedTech have been established, as well as first steps to develop a collaboration with UEMS and with the European Patient Forum (EPF).

In January 2019, the Task Force will be replaced by a permanent committee composed of Education Experts from our members societies, with the purpose to work on quality improvements of our educational activities.

Implementation of the Medical Devices Regulation and IVDR

In August, the Joint Research Centre (JRC) asked the Biomedical Alliance in Europe to provide feedback and recommendations to form advisory expert panels which would be responsible for the assessment of medical devices. We have nominated experts from our member societies that could be involved in the expert panels and have recommended the BioMed Alliance secretariat as liaison between the JRC and medical societies. Also, we have set up a Task Force on regulatory affairs and medical devices coordinated by Prof. Alan Fraser. The next step will be the meeting between the JRC's representatives and the BioMed Alliance TF's experts.