



REGULATIONS

Brighton Collaboration 2.0

20.05.2020

Regulation

This Regulation is based on the Brighton Collaboration's 2.0 Constitution of 20.05.2019.

I. Objectives of the Collaboration

Article 1. The Collaboration is a global network of partners with a shared commitment to facilitate the development, dissemination and evaluation of high-quality information about the safety of human vaccines. Specific objectives include:

- 1) To contribute to harmonization and standardization of vaccine safety assessment and reporting by:
 - a) Developing and publishing standard case definitions for adverse events
 - b) Developing and publishing guidelines for vaccine safety data collection, analysis, and presentation that can be applied in pre-and post-licensure settings including clinical research and pharmacovigilance in high, middle, and low-income countries
 - c) Developing tools to facilitate standard application of case definitions and guidelines
- 2) To facilitate the development of a functional global vaccine safety infrastructure across the lifecycle of vaccines [typically preclinical, clinical trials and post-licensure (signal detection, signal strengthening, hypothesis testing, risk-benefit communication, injury compensation)], synergizing with and complementing efforts of other stakeholders (e.g., WHO, MOH, industry) whenever, possible by:
 - a) Building and coordinating a global network of vaccine safety professionals
 - b) Creating an environment conducive to global collaborative research
 - c) Building scientific consensus among all major stakeholders to further the field and optimize the quality and timeliness of available information
 - d) Assisting building global capacity through education and international scientific support with a focus on low- and medium-income countries
 - e) Communicating the importance of and opportunities for globally concerted vaccine safety monitoring
 - f) Facilitating interaction of vaccine safety professionals around the world
 - g) Facilitating effective collaboration on outcome-oriented vaccine safety projects
- 3) To contribute to and support global vaccine safety communication by:
 - a) Providing a forum for clinical expert discussion related to current vaccine safety issues
 - b) Publishing a quarterly vaccine safety newsletter
 - c) Providing a global forum for peer review of adverse event case definitions, guidelines and summary vaccine safety data relevant to specific vaccine platforms
 - d) Providing a forum for enhancing general and political awareness of the globally increasing importance of vaccine safety monitoring
 - e) International consultancy services

II. Election of the Science Board

Article 2. Elections are conducted electronically on the Collaboration's website. Votes can also be submitted by mail (whether by paper or electronic media). The online election is based on candidate ranking through the voting body.

Article 3. Votes are registered if a member of the voting body submits a ranking number or an abstention for each candidate. Each number can only be used once, while "1" is used to indicate the first choice, followed by "2" for the second, etc. For each position, the candidate with the best (lowest) mean score is considered to be elected as the new member of the Steering Committee. A candidate is only elected if given a ranking (rather than an abstention) by at least half of the votes cast.

Article 4. Results of the election are confirmed for their accuracy by the Secretariat. Results will be communicated to all Partners two weeks after the deadline of the election.

III. Term of the Science Board

Article 5. The Board Members are elected for a term of 3 years. Board Members can be re-elected for 1 consecutive term. Board Members who have served on the Science Board for 2 consecutive terms may be re-elected again after a minimum period of 3 years off the board.

Article 6. Each Member elected takes office at the end of the term of the respective predecessor and continues in office for three years. In case of removal or resignation during a term, a Member elected will take up its seat with confirmation of the election results by the Secretariat.

Article 7. Board Members can resign from their office at any time by written notice to the Chair of the Science Board. Such resignation takes effect at the time specified in the notice, or if no time is specified, upon receipt of the notice.

Article 8. When a vacancy occurs prior to the end of the member's term, the Science Board can vote for a replacement member to complete the remaining term. The replacement can elect to sit for re-election at the end of the original member's term, by the usual processes.

IV. Offices within the Science Board

Article 9. Every Science Board member has a designated role, the board consists at least of:

- A Chair, Vice-Chair
- An Advisor for each of:
 - Standards and Harmonization (Case Definitions, Guidelines, and Safety Templates)
 - Clinical Assessment (Improving individual case management; CAFE, CISA-like Centers Networks)
 - Data Sharing [Improving risk assessment; (Networks) of Large-Linked databases
 - Capacity Building (in Low- and Middle-Income Countries; Building a network of Excellence; Fundraising)
 - Communication (VSQ)

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- Evaluation (of Brighton Documents/Tools)
 - Regulatory Authorities
 - Public confidence (promoting the understanding of public concerns)

Article 10. Chair and Vice-Chair are elected by the Science Board members and each serve a one-year term. The Vice-Chair will replace the Chair and a new Vice-Chair will be elected by the Science Board members.

V. Meetings and decisions of the Science Board

Article 11. A yearly schedule of the meetings will be set in advance and sent out electronically prior to the meeting.

Article 12 Teleconferences and similar meetings will normally be convened once a month. Detailed notification together with the agenda will normally be given at least one week before the date of conference calls. Special teleconferences may be called by the Chair or any two Board Members 14 clear days in advance or as agreed on by a majority of the Members.

Article 13. The Chair, Vice-Chair and Scientific Director (defined in the constitution Article 32) prepare the agendas and ensure the necessary documentation is available for all Science Board meetings. The agenda shall be approved by a majority of the Board Members participating in the respective meeting. With the same majority, the Board can add or delete agenda items.

Article 14. A decision to be voted on shall be decided on a verbal vote during teleconferences. A vote by email may be demanded by any Board Member.

Article 15. A declaration of the results of a vote by the Chair and an entry to that effect in the minutes of the meeting shall be conclusive evidence of the fact without proof of the number or proportion of the votes recorded in favor of or against the resolution.

Article 16. If a Board Member is disqualified in a specific matter, they must leave the meeting during the discussion of the item. The disqualified Board Member can submit a written memo concerning factual details on the matter to the rest of the Board Members before the discussion of the item.

Article 17. The minutes must be reviewed and approved by all Board Members in attendance. A Board Member who disagrees with a Board decision is entitled to have its opinion recorded in the minutes.

Article 18. The Vice-Chair is responsible for developing the action items and minutes. The secretariat (see Article 20 below) is responsible for archiving the minutes and other records and documents of the Science Board. In the absence of the Chair, the Vice-Chair will chair the meeting, in which case the responsibility for action items and minutes will be delegated to another Board Member.

Article 19. If found necessary, the Science Board can, within the framework of this Regulation, adopt rules of procedure.

VI. The Scientific Director and Secretariat

Article 20. The Scientific Director implements the strategic goals and objectives of the Collaboration, enables the Science Board to fulfill their governance functions, and gives direction and leadership toward the achievement of the organization's philosophy, mission, strategy, and its annual goals and objectives. The Scientific Director oversees and supports the activities of the Secretariat.

The Secretariat includes the Scientific Director, the SB Chair, the VSQ editor, and one to two designated others recruited by the Scientific Director and approved by the SB.

The Secretariat shall be in charge of the Brighton Collaboration's records and website; shall be responsible for mailings to its members and shall see to the proper audio recording of proceedings of meetings of the Science Board.

The Task Force shall be in charge of the Collaboration's funds, shall collect all member dues and assessments (if any), and shall follow established proper accounting procedures for the handling of the Collaboration's funds. The Scientific Director or a member of the Task Force shall report on the financial conditions of the Collaboration annually at Science Board meetings. At the end of the Task Force's fiscal year, the Task Force shall provide an annual audit report conducted by a certified public accountant.

The Scientific Director shall employ such members of the Secretariat as may be necessary to carry out the work of the Collaboration and fix the compensation of the Secretariat within the approved budget. The Scientific Director shall define the duties of the Secretariat, supervise their performance, establish their titles, and delegate responsibilities of management as shall in his or her judgement be in the best interest of the Collaboration.

VII. Brighton Collaboration Publications

Article 21: Brighton Collaboration official documents (here and after referred to *BC primary documents*) are defined as documents and tools developed within the framework and name of the Brighton Collaboration which have been developed by BC partners and require approval by the Science Board. These include: standardized AEFI case definitions; guidelines for data collection, analysis and presentation; vaccine safety templates developed by the Vaccine Viral Vector Safety Working Group (V3SWG); Vaccine Quarterly newsletter; and others as may be designated from time to time by the SB.

Article 22. All BC primary documents undergo a review by a Reference Group, made up of members of the Science Board as well as the Partners and selected external expert reviewers, as appropriate, responding to the call for peer review of the document, before they are finalized in the respective working group for use. Furthermore, feedback is solicited from users with actual experience of implementing *BC primary documents* in the respective study settings. Revisions to case definitions and guidelines will be made based on the feedback received. Contributions are given due credit in the acknowledgements unless authorship criteria are met.

Article 23. *BC Primary Documents* can be published in journals, books, or electronic media upon approval by the Science Board. All published *BC Primary Documents* will be made available on the Collaboration's website.

Article 24. Brighton Collaboration non-official documents (here and after referred to as *BC secondary documents*) are defined as scientific documents for publication or dissemination

(e.g., manuscripts, abstracts, study reports, or poster presentations) which are produced by one or more Brighton partners in the context of new or ongoing SB approved Brighton Collaborations or projects.

Article 25. The Science Board *should be informed, via the Secretariat, about all BC secondary documents* prior to being made public.

VIII. Authorship

Article 26. The Collaboration's authorship guidelines are based on the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals* established by the *International Committee of Medical Journal Editors*.

Article 27. Where appropriate, authorship should also be attributed to the respective working group. The working group itself is to be named as the main author. (e.g., "... on behalf of the Brighton Collaboration [AEFI] Working Group"). All participants in that group who are named as authors should fully meet the above criteria for authorship. Group participants who do not meet these criteria should be listed, with their permission, in the Acknowledgments or in an appendix.

Article 28. For manuscripts that are not considered *BC Primary Documents* (e.g., abstracts or manuscripts resulting from research projects initiated by a Brighton Collaboration working group), participants with significant contribution are to be named individually as authors.

Article 29. In publications of data derived from evaluation studies with significant contribution of the Collaboration, the Collaboration is to be acknowledged by mention of "on behalf of The Brighton Collaboration". Authors with a significant contribution to a manuscript are to be named individually. The Collaboration is entitled to refuse the association.

Article 30. The authors should determine the order of authorship. Primary authorship is determined by assessing the actual contributions in the conception, planning, and execution of the work. Sequencing the secondary authorship is determined by weighing the magnitude and salience of the input of the authors. Authors should be prepared to explain the order in which authors are listed. The order of authorship is decided as the paper is written. Challenge that may be encountered in determining authorship include:

- i) Changes in original assignments, circumstances, or contributions;
- ii) Increased numbers of participants including consultants;
- iii) Collaborators requesting authorship as the price for using their data;
- iv) Participants that fail to contribute as agreed;
- v) Supervisors, chiefs, or chairs demanding authorship by virtue of their positions.

The identified coordinator and team leader of the work in question will resolve authorship challenges

IX. Acknowledgements, citations, and references

Article 31. Individuals deserve recognition in the acknowledgements that have assisted the work by their encouragement and advice, review of draft documents, or editorial assistance. This includes in particular members of the Science Board, who are to be named individually in that capacity and by affiliation as well as participants in a working group, who contributed to a lesser degree to the development of a respective document or manuscript. The

reference group is to be acknowledged as a group. A link to the Collaboration website is to provide for further detail on its participants.

Article 32. Acknowledgement is also given for technical assistance and support or service personnel such as statistical assistants, photographers, illustrators, librarians, and substantial logistical or computer programming support, and for financial support.

Article 33. The Collaboration as such or the respective working group is to be acknowledged in manuscripts different from Brighton Document (e.g., manuscripts resulting from research projects initiated by a Brighton Collaboration working group) by mention of on behalf of the Brighton Collaboration.

Article 34. Quoting from publications requires a reference to the original work. The use of another's ideas, words, data, or analysis, or a reference to a precedent, must be cited in a way that others may find the originator or the contribution.

Signed,

[On behalf of the Brighton Collaboration Science Board and Secretariat]

XXXXX, Chair Date

XXXXX, Vice-Chair Date

XXXXX, Scientific Director Date