

## **Translation from German into English**

### **Articles of Association**

**(as amended on 31<sup>st</sup> July 2018)**

**Bundesverband Medizinischer Auftragsinstitute BVMA e.V.**

**(Federal Association of Contract Research Organisations)**

### **§1 Name, Registered Office**

1. The Association bears the name “Bundesverband medizinischer Auftragsinstitute (BVMA) e.V.”
2. The registered office of the Association is Munich.

### **§2 Object**

The Association has the following responsibilities:

1. To promote in the best possible way good clinical practice in clinical trials. This refers to any kind of clinical research on human subjects, whether before or after the approval of a product (e.g. drugs, medical devices, diagnostics, etc.) or a procedure (e.g. surgical intervention).
2. The development and representation of common positions on all questions of clinical research on human subjects.
3. The commitment of the members to a standard of quality assurance adopted by the general meeting.
4. To represent its members in legislative bodies and administrations at federal and national level as well as in the international area
5. Cooperation with professional societies and authorities for the purpose of improving - in a methodological and regulatory sense - drug research on human subjects, in particular with regard to ensuring the highest possible safety of the products and procedures used.
6. The promotion of education and training of all professional groups involved in clinical research on human subjects.
7. Public relations work with the aim of the appropriate treatment of clinical research on human subjects in the media.

### **§3 Membership**

1. Members can be legal entities under civil law as well as partnerships which support the objectives of the Association and have been commercially active in the field of planning/conducting/analysing or quality assurance of clinical research and related areas on human subjects for at least 2 years.

In exceptional cases, if the contract research organisation is not a legal entity or partnership, but otherwise meets all the requirements for admission, a natural person can alternatively also become a member, but only one person per contract organisation. There is no entitlement to membership in the Association.

2. Membership is acquired by

- written application to the Association,
- the provision of two supporters from among the members, but no members of the Executive Board,
- the provision of proof of quality in accordance with the established procedure
- the subsequent acceptance of the application by the Executive Board.

Furthermore the membership will be bound to payment of the admission fee. If it is not possible for a candidate for membership to identify two recommendations from the circle of members (non-members of the association's executive board), two external references must be given. The Executive Board decides on the acceptance of the references.

3. Applicants will only be admitted if they are in a position to make a contribution in their field of work based on the state of the art, while respecting and taking account of the relevant laws, the legal decrees issued in this connection as well as any other pertinent national and international guidelines and recommendations of a scientific and ethical nature. Applicants must, furthermore, undertake to abide by the resolutions of the Association and its Code of Conduct.

Any review, in particular of the quality assurance standards laid down by the Association as provided in § 2 (3) shall be conducted by an external organisation. The regulations for carrying it out will be drawn up by the General Meeting.

4. Membership will expire:

- a. in the case of members which are legal entities, by their dissolution
- b. in the case of natural persons, upon their death or on cessation of the contract research activity of the contract organisation represented by the person
- c. by written resignation tendered in compliance with a notice period of three months to the end of a calendar year
- d. by exclusion, which can be declared for due cause by the General Meeting. A precondition for exclusion shall be a request made by a member to the Executive Board and substantiated in writing. The excluded party will be entitled to file an objection within one month of notification of exclusion, which will be decided upon at the next General Meeting. Membership will be suspended until such time as the General Meeting has come to a decision. A due cause shall be deemed to be in particular:
  - contravention of the quality standards of the Association
  - contravention of the Code of Conduct of the Association
- e. by exclusion, which can be declared by the Executive Board for failure to pay the membership fee within three months of its due date. The attention of the defaulting member will be drawn in writing in advance to the imminent exclusion.
- f. upon institution of insolvency proceedings against a member or in case of no proceedings being instituted for lack of assets.

#### **§4 Provision of Funds**

1. The funds for meeting the Association's expenses will be derived from the admission fee and annual membership fees. The admission fee and/or membership fees will be fixed in advance by the General Meeting. In addition, the Association shall have the option of raising funds by organising professional events.
2. The membership fees shall be due and payable at the beginning of each financial year. Upon resignation of a member during the financial year, the fee already paid will not be refunded, not even on a pro rata basis.

#### **§5 Governing Bodies**

The governing bodies of the Association shall be:

1. the Executive Board
2. the General Meeting

#### **§6 Executive Board**

1. The Executive Board shall consist of one Chairman, one Vice-Chairman and one other Executive Board member. They will be elected by the General Meeting for a term of two years. Re-election is permitted.

Persons having an interest in an Executive Board position shall apply in writing to the association's office stating the preferred position at least four weeks in advance of the General Meeting. The association's office forwards the application to the members within two weeks upon receipt in order to notify the members. The election will take place directly at the General Meeting no matter how many applications are available. Upon agreement of the General Meeting, an ad hoc application at the General Meeting is possible.

The Executive Board will in any case remain in office until the new Executive Board is elected.

If a member of the Executive Board retires before the end of the term, he or she will be replaced by the next highest ranking Executive Board member. Should a further member be required, the Executive Board will itself elect a substitute member for the remaining term of office.

2. The Executive Board will constitute a quorum, if the Chairman of the Executive Board and one other Board member are present. Resolutions of the Executive Board will be adopted by simple majority – unless otherwise stipulated in these Articles of Association. In the event of a tied vote, the Chairman will have the casting vote. Resolutions may also be adopted in written form (letter or e-mail).
3. The Association will be represented by the Chairman of the Executive Board on his/her own or jointly by two other members of the Executive Board in compliance with Art.26 BGB (Bürgerliches Gesetzbuch = German Civil Code). The Executive Board will in particular be responsible for
  - a. management of current business
  - b. representing the Association both internally and externally

- c. convening the General Meeting and compiling the agenda
  - d. implementing the resolutions of the General Meeting
  - e. supervising the finances/preparation of budgets
  - f. clarifying questions relating to compliance with the Code of Conduct
  - g. deciding on the admission of new members.
4. The acquisition, sale and mortgaging of land, acceptance and granting of loans, incurrence of bills of exchange outstanding and guarantees, all pledges and mortgages, participation in other associations or institutions shall require the prior consent of the General Meeting.

### **§7 General Meeting**

1. The regular General Meeting will be held at least once a year and convened one month in advance in writing or by e-mail by the Chairman of the Executive Board, giving details of the agenda, as provided by Art. 32 BGB. Extraordinary General Meetings will be convened by the Executive Board or at the request of at least one third of the members, also one month in advance.

The Chairman of the Executive Board will preside over the General Meeting; if he or she is prevented from attending, the Vice-Chairman or the other Executive Board member will preside over the Meeting. If no members of the Executive Board are present, the meeting will itself appoint its chair by simple majority of the votes cast.

2. The General Meeting will constitute a quorum, if at least half of the members entitled to vote or their proxies are present. Every member present may at most represent one other member. The authorisation to act as proxy shall be given in writing. Unless otherwise stipulated in the Articles of Association, resolutions will be adopted by simple majority, with each member having one vote. Members, the majority of whose shares belong to another member, will not have a separate vote. In the event of a tied vote, the chairman of the Meeting will have the casting vote.

If a General Meeting does not constitute a quorum, a new meeting shall be convened on the same day with the same agenda, and it will constitute a quorum irrespective of the number of members present. Reference shall be made to this provision in the invitation.

3. Any resolutions relating to the fixing of the admission fee and membership fees, dissolution of the Association, amendments to the Articles of Association, as well as exclusion of a member by the General Meeting and dismissal of the Executive Board shall require a majority of two thirds.
4. Minutes will be taken of the Meeting. They will be signed by the secretary and Chairman of the Executive Board and a copy sent to the members.
5. Alternatively, the General Meeting can pass its resolutions in written form (letter or e-mail), if the Chairman of the Executive Board or at least one third of the members so desire. An appropriate period will be set for the submission of the replies. Failure to reply, even after a repeated request, will be deemed to be an abstention.

### **§8 Honorary Membership**

An honorary member is a natural person proposed by the Board of Directors or at least three member companies who, by secret ballot, obtains a majority of two-third at the General Meeting. The appointment of an honorary member is based on extraordinary merits of the person for the association. The honorary member may participate in all activities of the Association, but has neither a

passive nor an active right to vote. An honorary member is exempt from the quality certificate and the membership fee. The duration of the honorary membership is unlimited, but can be terminated by a simple majority decision of the General Meeting at the request of a member company. The honorary member may resign from membership at any time.

### **§9 Financial Year and Financial Statements**

1. The financial year shall be the calendar year. Within five months of the end of the calendar year, the Chairman of the Executive Board will prepare an annual statement of account based on properly maintained records of income and expenditure, as well as statements of assets and liabilities, and will submit the same to the General Meeting once they have been audited by the auditor.
2. The auditor will be elected by the General Meeting for a period of two years. Re-election is permissible.

### **§10 Miscellaneous**

The management of the Association's affairs must be aimed at exclusively and directly fulfilling the objectives stipulated in the Articles of Association.

The Association shall operate in a selfless manner and shall not pursue primarily profit-making objectives.

Members may not receive any contributions from the funds of the Association. No person may benefit from expenditure unrelated to the aims of the Association, or from disproportionately high remunerations.

If the Association is dissolved, the assets of the Association will fall to an institution specified by the General Meeting, which pursues the aim of promoting science and research.

The foregoing is an unofficial English translation of the original German Articles of Association and has no legally binding effect.