

THE ITALIAN ASSOCIATION
of CROs and Service Providers for Clinical Research

STATUTE

NAME AND HEADQUARTERS

Article 1.

The "Associazione Italiana Contract Research Organization and Service Providers for Clinical Research ", with acronym, "AICRO plus", is hereby established.

Article 2.

The association has its headquarters in Milan, Piazza Meda 3.

OBJECTIVES OF THE ASSOCIATION

Article 3.

The Association, as part of its applied clinical research activity, aims to:

Promote the use of G.C.P. (Good Clinical Practice) in clinical trials, and other reference regulations (GLP, GMP etc.) as well as national and international guidelines, where applicable.

To represent the common positions of the members on issues concerning clinical research.

Ensure quality according to a standard set by the Members' Assembly.

Representing Members before the competent authorities, whether local, national or international.

To collaborate with other competent authorities and/or recognised Orders and Associations in order to further develop clinical research.

Promoting the training of personnel involved in clinical research.

To provide correct information about clinical research through the media.

To realise these objectives, the Association maintains a dialogue with the representation of the Medical Orders, the Pharmaceutical Industries, the media and the competent authorities.

In particular, the Association wants to ensure the interests of patients, but also the continuous development of scientific methodology.

To this end, Symposia, Seminars or Conferences of the Association may be organised, as well as regular refresher courses.

In order to ensure a high level of quality, in addition to complying with the provisions of the relevant legislation in force, the Association's Board of Directors, representing the Members' Assembly, will establish an "AICRO plus Quality Regulation", within which it may include any additional quality requirements that Members must comply with and adhere to.

MEMBERSHIP

Article 4.

Capital companies (Italian or foreign with a permanent organisation in Italy) that agree with the objectives of the Association may become Members.

The Executive Board has the power to appoint as Honorary Members individuals who have particularly distinguished themselves through their scientific contribution within the Association or in the field of clinical research, demonstrating competence, commitment and professionalism.

The honorary member is exempt from paying the annual membership fee.

The Honorary Member may attend the Annual Convention, may attend the Assembly of Active Members, but has no right to vote or to stand for elective office within the Association.

In order to become a Member, a written application must be submitted, together with documentation certifying the quality of the Society, as required by these Articles of Association and the "Rules and Regulations".

The control and verification of the requirements, to be carried out within thirty days of receipt of the application, is the responsibility of The Executive Board in the name and on behalf of the Members' Assembly.

In order for AICRO plus membership to be valid for all purposes, the accepted Member must then pay the membership fee, which will be valid as a membership fee for the current year, and will be required to pay the membership fee for the following years. The amount of the membership and registration fees is laid down in the "Rules and Regulations".

All members are entitled

- to effectively attend the Association's life;
- Attend the General Meeting with the right to vote, with the exception of honorary members;
- to access the Association's offices, except for honorary members;
- to inspect all resolutions and documents relating to the management of the Association, with the possibility of obtaining copies;

All members are bound

- to observe these Articles of Association, any internal regulations and the resolutions legally adopted by the Association's bodies;
- to attend the Association, cooperating with the Association bodies for the realisation of the Association's purposes;

- to always maintain a correct behaviour towards the Association and not to implement initiatives that are in contrast with the aspirations that animate its activity;
- to pay the annual membership fee.

Article 5.

Members that change their company name, including as a result of mergers, amalgamations or acquisitions between companies present in AICRO plus, are required to submit a written notice to AICRO plus. If the payment of the annual membership fee has already been paid, such payment shall be recognised as valid for the current year for the company resulting from the change of company name. The payment made for the current year by the merged company shall be acquired by the Association, with no possibility of reimbursement.

Article 6.

A Member shall lose its status in the event that:

- a) He ceases to carry out his activities within the scope of the Association's objectives.
- b) Is subject to bankruptcy proceedings.
- c) By decision of the Member itself by written declaration
- d) For serious reasons such as:

Violation of the quality standard laid down by the Association in the "Rules and Regulations" pursuant to Article 3 above.

Violation of the code of ethics established by the Association as set out in Article 4 above.

Failure to pay the membership fee within 3 months after the due date and after having been reminded of the payment by written communication by the Executive Board.

Without prejudice to the aforesaid rights and duties, the Association guarantees to all Members the uniform regulation of the membership relationship and of the associative

modalities aimed at guaranteeing the effectiveness of the relationship, expressly excluding the temporary nature of participation in the life of the Association and providing for associates or participants over the age of majority the right to vote for the approval and amendment of the articles of association and regulations and for the appointment of the Association's governing bodies.

ASSETS AND FINANCING OF THE ASSOCIATION

Article 7.

The Association's patrimony is indivisible; from it the Association draws the economic resources for its functioning and for carrying out its activities.

The funds required for the Association's activities shall be raised from the membership fees, the annual dues of the Members, sums collected from any cultural initiatives, and sums deriving from any donations. Private donations must be examined and submitted to The Executive Board for approval.

Annual dues must be paid at the beginning of each year and cannot be refunded. Current and representative activities carried out by members for the benefit of AICRO plus shall, however, be free of charge, unless explicit exceptions are approved by The Executive Board. Annual membership fees and/or contributions are non-transferable, with the exception of transfers due to death, and cannot be subject to revaluation.

The Association is forbidden to distribute, even indirectly, profits or operating surpluses however denominated, as well as funds, reserves, or capital during the life of the Association

itself, unless the destination or distribution is imposed by law or is made in favour of other bodies that by law, statute, or regulations are part of the same and unitary structure.

The Association must use any profits or surpluses for the realisation of its institutional activities and those directly connected to them.

ORGANS OF THE ASSOCIATION

Article 8.

The organs of the Association are:

1. The Members' Meeting
2. The Executive Board

The Members' Meeting

Article 9.

a) The Ordinary General Meeting of Members is convened at least once a year by means of an official invitation with thirty days' notice (reduced to six days in the case of urgent convocation) and by the sending in of the agenda in writing (letter or e-mail) by the President of the Managing Committee.

Members of the Executive Board are entitled to attend the General Meeting.

Extraordinary meetings of the Members' Assembly take place following a convocation by the Managing Board or at the request of at least one third of the Members, in both cases with thirty days' notice. The Extraordinary General Meeting shall be responsible for the matters laid down in the Civil Code, in particular amendments to the articles of association and the dissolution of the Association and the appointment of the liquidator, if any. The extraordinary meeting is valid with the presence of at least half plus one of the members and resolves with the majority of those present.

Provision is also made for General Meetings to be held via teleconference.

b) The Members' Meeting may validly decide when at least half of the Members are present, in person or by proxy.

Each Member present may represent a maximum of one other Member by written proxy.

Decisions, unless otherwise specified, are taken by a simple majority of the votes of those present.

c) Should the Shareholders' Meeting lack the prerequisites to be able to validly pass resolutions, a second meeting of the Shareholders' Meeting may be scheduled at the same convocation, with the same Agenda, but with at least one day's difference (this also applies to urgent convocation). At the second convocation, the General Meeting may pass resolutions regardless of the number of Members present, provided that one of the members of the Managing Board is present.

d) The Ordinary General Meeting resolves:

On any amendments to the "AICRO plus Rules and Regulations".

Appointing the members of the Executive Committee

Approval of the balance sheet and budget.

Other matters delegated to it by the Executive Committee, the law, or these Articles of Association.

e) At each meeting of the General Assembly, the minutes of the General Assembly shall be drawn up and signed by the Secretary of the meeting, appointed by the General Assembly, and by the President of The Executive Board. Copies of the minutes shall also be sent to the Members.

f) The Members' Meeting may make its decisions in writing (letter, e-mail), if the President of the Managing Committee or at least one third of the Members so request.

The Executive Board

Article 10.

a) The Executive Board (CD) is the administrative and management body of the Association. It consists of five board members who are natural persons of full age and have the following qualifications: a President, a Vice President, a Scientific Director, a Treasurer and a Board Member. They hold office for three years and are eligible for re-election. With the exception of the first ones appointed in the articles of association, the assembly appoints the President, the Vice President and the other three Board members. The Executive Board, thus appointed, appoints the Treasurer and the Scientific Director at the first useful meeting. In the event of a vote in which no majority emerges, the President's vote shall prevail. A member of the Executive Board or, in case of unavailability, another member deemed suitable by the Executive Board, shall also be entrusted with the task of representing the Association internationally.

b) The Executive Board can validly decide with the attendance of at least three of its members.

c) Decisions can also be made in writing (letter, e-mail) without the board meeting being necessary. In the event of a tie, the vote of the President prevails. It is the president's responsibility to keep a book in which all decisions taken by The Executive Board are chronologically recorded.

d) The executive committee is responsible for the following activities:

1. Managing current activities.

2. Representing the association vis-à-vis the Members themselves and third parties.
3. Drawing up, amending and enforcing the "Rules and Regulations" in accordance with the instructions of the Assembly.
4. Organising the Members' Assembly and planning and organising Symposia and other cultural initiatives.
5. Carrying out the decisions taken by the Members' Assembly.
6. Monitoring the correct economic and financial performance of the association.
7. Deciding on the acceptance of new Members.

In the event that one of the members of The Executive Board ceases to serve, the members remaining in office must without delay convene the Assembly for the replacement of the missing Board Member. Pending replacement, the Board Members remaining in office may perform the acts of ordinary administration.

FINANCIAL YEAR AND YEAR-END BUDGET

Article 11.

The financial year of the Association coincides with the calendar year. Within 6 months after the end of the year, the President of The Executive Board shall draw up an annual budget based on income and expenditure, the level of assets and any debts, and submit it to the General Assembly for approval.

DISSOLUTION

Article. 12

If the General Meeting resolves to dissolve the Association, The Executive Board, or the liquidator appointed by the General Meeting, if any, shall dispose of the Association's assets and devolve them in accordance with the following paragraph.

In the event of the Association's dissolution, the residual corporate assets shall be allocated to another association with similar purposes or for purposes of public utility, unless otherwise required by law. It shall then be devolved, upon indication of The Executive Board or of the liquidator eventually appointed by the Assembly, to a foundation, association, or other non-profit organisation that pursues purposes similar to those of the Association.

REFERENCE

Article. 13

For anything not expressly provided for in these Articles of Association, the provisions contained in the Civil Code and in the relevant laws in force shall apply.