



Association of CROs active in Sweden

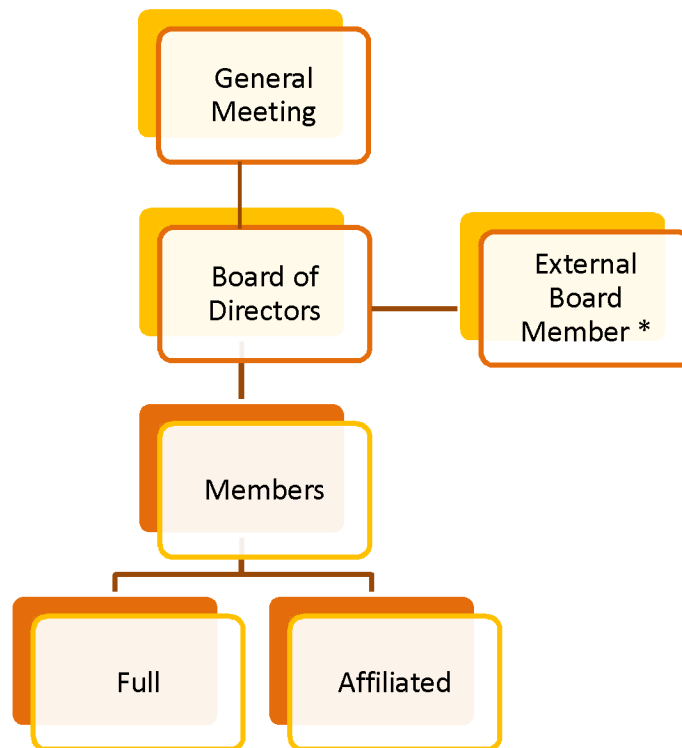
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§1 Name and Organization

The association is called ASCRO (Association of CROs active in Sweden). ASCRO was formally formed on 29 September 2011.



* External Board Member is an optional position

The following definitions apply for this document:

Term	Definition
Association	The Association for Swedish CROs – ASCRO
CRO	Contract Research Organization – a legal entity; business providing services to the academia, the pharmaceutical, biotech and medical technology industry
Full Member	A legal entity fulfilling all criteria for membership in ASCRO – holding formal voting power
Affiliate Member	A legal entity not fulfilling all criteria for membership in ASCRO – however granted a non-voting membership
Industry	Pharmaceutical companies and other companies conducting research within the field of life science

§2 Objective and means

ASCRO shall:

- act as an interest group and voice for CROs active in Sweden and providing consultancy services to academia, the pharmaceutical, biotech and medical technology industry
- represent and promote the common interests of its Members towards sponsors, governmental agencies/bodies, research organizations and similar entities
- be an active player in the provision of information, in lobbying to influence political, public, industry and other decision makers in matters of importance for its Members and public interests relating to life science and clinical trials
- serve as a facilitator and can organize meetings and conferences as a means for dialogue between its Members, the Industry, the Health Care Providers and other parties of interest to ASCRO and its Member Companies
- act to strengthen the position of the CRO as a key research entity in Sweden
- promote training, education and mentoring for the CRO industry
- promote the development of tools, techniques and technologies for state of the art recruitment of investigators and patients into clinical trials

§3 Membership

Candidates applying for a full membership in ASCRO should fulfill the following:

1. a legal entity providing consultancy services to academia, the pharmaceutical, biotech and medical technology industry
2. pay the membership fees to ASCRO (as set forth by the AGM) and able to contribute to the objectives of ASCRO
3. follow ASCRO's lead words: Quality, Ethics, Standards
4. have a quality management system in place (i.e. working instructions, SOPs)

A legal entity in Sweden who fulfills 1-3 above only, can apply for an affiliated membership.

All Members are subsequently reviewed and accepted for membership by the ASCRO Board of Directors and membership is granted. Each Full Member and Affiliate Member should nominate one named employee to act as its representative in the association.

The Board will keep a register in which the names and addresses of all Full Members and Affiliate Members are listed. In this register it will also be stated which director or representative of a Member Association represents the Member in the bodies of the Association.

The membership year will run from 01 JAN – 31 DEC.

§4 Termination of membership (Full and Affiliate Member)

Membership will end:

- if the Member – legal entity ceases to exist, is declared bankrupt or granted moratorium of payments
- by termination by the Member
- if the Member does no longer fulfil the criteria for membership as determined by the Board of Directors

Termination of a membership must take place in writing (e-mail acceptable) through formal communication between the Member and a representative of the ASCRO Board.

If the membership ends during the financial year, the annual contribution/fee is still owed in full by the Member, unless the Board decides otherwise.

The Board can suspend a Member:

- if the Member acts in violation of; or fails to comply with:
 - the intent
 - or articles of the Association
 - or any other obligation of a Member
- or if actions by the Member harms the Association in an unreasonable manner

§5 Board of Directors: composition and nomination

The Board of Directors are appointed by an Annual General Meeting (AGM). Only representatives of companies with full membership can be elected as members of the Board of Directors.

In addition, the Board of Directors may choose to appoint a contracted external board member.

- The Board consists of a maximum of five (5) members, plus an optional external member.
- The nominating committee is responsible for identifying Board candidates, including the Chairman of the Board. The candidates are presented during the AGM.
- The nominating committee is appointed at the previous AGM and should consist of at least two members.
- The Board of Directors will constitute themselves on their first meeting after the AGM. This first meeting is to be held in conjunction with the AGM. During this meeting the Board of Directors will by vote name one of the Board of Directors to serve as the Treasurer. The Board of Directors may also choose to appoint other positions, as they see fit.
- The Board should preferably consist of members from both local Swedish CRO's and of multinational CRO's. In addition, the Board may choose to appoint one external member with relevant knowledge and experience needed by ASCRO.

The Board members elected by the AGM are appointed for a period of two years.

The Board shall:

- set forth for the approval of the AGM the association strategy, budget and framework for activities
- manage the association in accordance with its by-laws and the direction and priorities set forth by the AGM
- represent the association externally
- appoint committees/working groups/experts for certain tasks if and when needed and also provide work instructions for any such group or person
- manage and control the finances of the association

The Board of Directors is accountable to the AGM.

§6 External Board Member

When an external board member is appointed, this person will be a consultant to ASCRO and does not have to be an employee of one of the Members. This position may be filled if ASCRO Board of Directors deems this is needed to fulfil the goals of the Association and to support the work of the Board of Directors. The work to be performed by the external board member will be governed by a written contract and a role description. The external board member can be elected the Chairman of the Board of Directors by the AGM, but does not necessarily need to hold this position. The position will be filled by recruitment and decision made by the Board of Directors.

§7 Annual General Meeting (AGM) and Board meetings

A member meeting is the key operational forum of the association. Such meeting is constituted by the named representatives of the Members.

The executive body of the association is the Annual General Meeting (AGM):

- held at minimum once a year and within a given time frame after the end of the Association financial year
- the AGM takes place per notice given in writing to the Members with a notice period of at a minimum 30 days
- the AGM approves the association strategy, budget, fees, possible changes to these by-laws, and framework for activities
- the Members and their employees have access to member meetings and the AGM
- only the named individual acting as the Member ASCRO representative or his/her nominee will have voting rights
- any board member can call for an additional AGM
- Board meetings will be held at least 4 times a year

Minutes from each AGM will be kept by a meeting Secretary and confirmed and signed for approval by the meeting secretary and two reviewers appointed during each meeting.

Meeting minutes from each Board of Directors meeting will be kept by a meeting Secretary and confirmed and signed for approval by the meeting Secretary and one reviewer. Wet-ink signatures are not required.

Each Full Member has one vote and Affiliate Members do not have voting rights. All decisions of a Member meeting and the AGM are taken with full majority of the votes cast.

§8 Associate membership in LIF

The life science industry in Sweden has established a self-regulatory system to maintain high and consistent business ethics and credibility. The system includes but is not limited to agreements and rules governing the collaboration between parties including industry and health care. The Association of Swedish Pharmaceutical Industry (LIF) has entered into several agreements on the interaction between parties in clinical trials and national health registries. Further there are rules governing the interaction between industry and politicians. Details of the system can be found [here](#).

Through the association between LIF and ASCRO a member of ASCRO is by membership bound to comply with the rules and regulations of the self-regulatory system and to without limitation comply with any ruling of IGM or NBL and to pay to ASCRO any associated fees/penalties.

The ASCRO Board of Directors shall appoint a contact person towards LIF.

§9 Financial year, annual report, account and justification

The financial year of the Association is 01 JAN – 31 DEC. The Board will present its annual report at the AGM and will provide accounts and a balance sheet and a statement of income and expenses. An auditor can be used to examine, report and sign off on the accounts and justifications, but this is not required.

The association should be non-profitable and in the case of a redundancy the excess funds should be used to the benefit of the Members, e.g. arranging common activities, seminars, or to adjust the membership fees.

§10 Dissolution

The Association may voluntarily dissolve and cease to operate upon the affirmative vote of not less than seventy-five percent (75%) of the voting Members present at any AGM, provided all Members have been notified of this purpose together with the summons to the AGM. Upon dissolution, any net assets of the Association shall be distributed back to the Members of the association.