



## Membership bylaws of the Swiss Clinical Trial Organisation (SCTO)

These membership bylaws are based on Article 3 of the current version of the SCTO bylaws. This document is also available in German and French. Only the printed and signed English version is legally binding.

### Article 1 Membership categories

<sup>1</sup> Ordinary members are:

- founding member institutions of the SCTO
- not-for-profit institutions and organisations with the capacity for quality assurance, data management, statistics and methodological support and with an official performance mandate for clinical research
- the treasurer (an individual from a founding member institution).

<sup>2</sup> Associate members are:

- not-for-profit institutions and organisations involved in clinical research. Commercial contract research organisations and pharmaceutical companies do not, as a general rule, qualify for membership.

### Article 2 Membership application procedure

<sup>1</sup> First, an applicant shall approach one of the ordinary members that will then function as its advisor for the application process. Second, the applicant shall work closely with this ordinary member in order to submit the following:

- a completed application form
- an official recommendation letter from the applicant's institution or organisation
- proof of a quality management system (QMS) implemented in accordance with the SCTO's GGOP<sup>1</sup> and national regulations as well as proof of an external audit of this QMS
- for associate membership: a signed agreement with one of the Clinical Trial Units (CTUs) from the CTU network. This agreement regulates future cooperation and ensures that the QMS (including the services covered thereby) is continuously adjusted to new circumstances.
- proof of an implemented data management system that meets the requirements of GGOP.

The completed application shall then be submitted to the President of the SCTO. On receipt of the application, the

President informs the Steering Board and adds the application to the agenda of the next scheduled Steering Board meeting. A representative of the applying institution or organisation is invited to this meeting in order to answer questions. If deemed necessary, one or more delegates from the Steering Board may also visit the applicant in order to gather further information. The ordinary member acting as the advisor for the application process can recommend the applicant as a new member to the Steering Board at the next Steering Board meeting. At the following Steering Board meeting the President finalises the election of all open applications.

<sup>2</sup> Membership starts immediately after the approval of the application.

### Article 3 Application fee

<sup>1</sup> The Steering Board determines the application fee. The application fee is payable even if an application is rejected.

### Article 4 Payment of annual membership fee

<sup>1</sup> All members must pay an annual membership fee according to their membership category. The fees are determined during the General Assembly each year.

<sup>2</sup> A full annual membership fee is payable irrespective of the date of admission or termination of membership.

<sup>3</sup> The annual membership fee is not refundable once it has been paid.

### Article 5 Register of members

<sup>1</sup> The SCTO shall maintain and publish a register of members.

### Article 6 Rights and duties of members

<sup>1</sup> **Ordinary members:** Ordinary members of the SCTO shall have the rights and duties as per the current SCTO bylaws, including all the rights of associate members mentioned below. The SCTO's operational standards as adopted by the Steering Board (including data management, monitoring and education) are binding for ordinary members.

<sup>1</sup> SCTO Guidelines for Good Operational Practice, current version

<sup>2</sup> **Associate members:** In addition to the rights and duties outlined in the SCTO's bylaws, associate members of the Association shall have the following rights and duties:

a. Rights:

- Participate in events and training organised by the SCTO
- Access to all documents prepared by the SCTO (e.g. guidelines, templates and SOPs)

b. Duties:

- Agree to continue working together with the CTU advisor (an ordinary member) after admission
- A mandatory meeting with the CTU advisor at least once a year

<sup>3</sup> Members must actively contribute to the different working groups of the CTU network on request from the SCTO (quality assurance, data management, education etc.).

<sup>4</sup> The SCTO will act to represent the interests of all membership categories in its function as the central cooperation platform for clinical research in Switzerland.

## **Article 7 Amendments to the bylaws**

<sup>1</sup> These bylaws may be amended when necessary by a simple majority of Steering Board members. Proposed amendments shall be submitted to the President and then distributed with regular Steering Board announcements.

## **Article 8 Approval of the bylaws**

<sup>1</sup> These bylaws were approved by a simple majority vote at the Steering Board meeting on 14 September 2012 and revised on 1 December 2015.