

# **STATUTES**

**Slovak Association of Clinical Research Organizations and Professionals  
(SACROP)**

**Bratislava, 03.06.2015**

## I. Basic provisions

1. The name of this civic association is:

**Slovak Association of Clinical Research Organizations and Professionals**

The abbreviation is: **SACROP**.

2. The seat of the civic association **SACROP** is Senecká 114,90024 Veľký Biel

3. The civic association **SACROP**, /further just association/ is an independent association, formed based on the law no. 83/1990. on association of citizens, as amended in its current form, which may in its own name and by its own actions acquire rights and obligations, create branches in the country of origin and perform any other tasks in accordance with generally binding regulations.

**4. On behalf of the association, the following persons are entitled to act:**

\* Angelika Schmiedlová, [REDACTED] [email: angelika.schmiedlova@stylestrade.sk](mailto:angelika.schmiedlova@stylestrade.sk) phone: **0903 721 690**

\*Board members

## II. Purpose and activities

1. The principal objective of the association is to unite subjects based on common professional interests dealing with clinical research and development of humane medicinal products.

2. To fulfill the objectives defined in paragraph 1 of these statutes, activities of the association will particularly consist of:

a) association of natural and legal persons whose activities lie in the field of clinical research and development of humane medicinal products and medical devices,

b) promotion, representation and protection of the common interests of its members in relation to governmental institutions and organizations active in the field of clinical research, particularly in negotiations with the Ministry of Health, State Institute for Drug Control, Ethics Committee, health insurance companies and other organizations entering into the field of clinical research,

c) submission of comments on legislation related to clinical research and to propose legislative adjustments,

d) to provide technical advisory activities for its members and to mediate an exchange of experience between members of the association,

e) to encourage the exchange of knowledge and information related to clinical research with public and professional organizations and societies, patient associations, the media and so on...,

- f) to engage in close contacts with relevant institutions and governmental bodies and to notify them about the opinions and suggestions passed within the association,
- g) in issuing publications, supporting documents and aids necessary to ensure the operation and the achievement of the objectives of the association,
- h) in cooperation with other establishments, institutions and organizations, whose purpose and goals correspond with the objectives of the association,
- i) to support the organization and carrying out of social actions and events supporting the objectives of the association,
- j) the acquisition and the use of financial resources earmarked to achieve the objectives of the association.

3. The activities and objectives of the association will be updated and newly specified in the medium-term operating plans and annual plans of action, approved by the association members.

4. In carrying out of the activities of the association, all generally binding legal regulations and by the legislation imposed obligations must be respected.

### **III. Membership**

1. Members of the association may be subjects complying with its aim and objectives, as specified in paragraph II. of these statutes. This is demonstrated by the subject in question by submitting his Trade Certificate or Certificate of incorporation.

2. Members of the association may be natural or legal persons, who carry out active work in the field of clinical trials of medicinal products or medical devices in Slovakia

3. An natural or legal person that wishes to become a member of the association can manifest his interest by sending a completed application form to the headquarters of the association. The association has the right to ask an applicant for membership of some additional information, concerning the conditions for the establishment of the membership. About the membership of the applicant decides the board within 30 days of the receipt of the application and proof of payment of the membership fee. The applicant is informed about the admission for a member via e-mail.

5. The annual membership fee is included in the updated version of the document **„The conditions for membership and voting in SA CROP“**

6. The annual membership fee is paid in advance for each calendar year in full, but not later than the 31st of January of the current year. The annual membership fee for new members is paid in full irrespective of the time of the year, or how long the membership in the association lasted.

7. Changes of the membership fee are decided by the assembly of members.

8. The board maintains a list of members of the association,

which contains the following information :

\*name and surname, or business name

- \* company ID
- \* permanent residence or seat
- \* email / phone contact
- \* date of entry into the association

and the entered personal information of members and personal data are protected according to special legal regulations.

9. Membership in the Association ceases when the following occurs:

- \* voluntary withdrawal valid since the date the association was notified in writing,
- \* death of a natural person or the dissolution of legal subjects,
- \* dissolution of the association,
- \* expulsion due to the non-payment of the membership fee until the 31st of March for a given calendar year and after non acceptance of the send reminder to pay the membership fee within one month, i.e. until 30th of April of that year,
- \* Exclusion if a member repeatedly and despite warnings does violate the code of ethics and membership obligations, or for other important reasons.

10. The exclusion of a member from the association is definitively decided by the board.

11. A member, whose membership in the association ceased to exist, is not entitled to a refund of the already paid membership fee.

12. An member of the Association may be represented by an authorized representative who is a member of the association on the basis of a written authorization.

#### **IV. The rights and obligations of members**

1. An member of the association is entitled in particular to:

- a/ to be familiar with the statutes and other internal regulations of the association,
- b/ to be informed about the activities and decisions of the association,
- c/ to attend and participate in activities of the association,
- d/ to administer personal, material, organizational and other suggestions,
- e/ to vote and to be elected to the bodies of the association,
- f/ to propose a candidate to the various bodies of the association.

2. A member of the association must in particular:

- a/ adhere to the statutes of the association and the Code of Ethics,

- b/ meet the conclusions and decisions of the association,
- c/ adhere to financial discipline and economical principles,
- d/ responsibly and conscientiously operate in the association bodies,
- e/ regularly, responsibly and conscientiously participate in the activities and operations of the association, helping in meeting the objectives of the association,
- f/ properly and timely pay the membership fees,
- g/ protect and enhance the assets of the association.

3. A member of the association - natural or legal person is meeting the rights and obligations under the statutes through its statutory body, or a person designated for it.

4. The surname and name of members of the association will be included in the list of association members. The list of members may be published on the website of the association.

## **V. Bodies of the Association**

1. The bodies of the association are:

- a/ the assembly of members
- b/ the association board
- c/ the workgroups or project teams
- d/ the revision board

## **VI. Assembly of members**

1. The assembly of members is the supreme body of the association and it is made up from all members of the association.

2. The assembly of members decides on all fundamental issues, in particular:

- a/ it approves the statutes of the association and all their amendments,
- b/ it elects and dismisses members of the board,
- c/ decides on the termination of the association by voluntary dissolution of the association and the settlement of its assets.

3. A session of the assembly of members is summoned by the board of the association as necessary, but at least once every two years. The board convenes an assembly of members of the association if it is requested by

- \* All the members of the revision board
- \* 20 % of all members of the association

so that it is held in one month from the receipt of the request.

4. The Assembly of members shall constitute a quorum when:

- a/ if more than half of all members are present

b/ If the previous assembly of members did not constitute a quorum, the following properly convened assembly of members shall constitute a quorum at any number of the members present

The assembly of members decides by a majority of present members of the association.

5. Each member of the association has a proportional number of votes specified in the currently valid document „**The conditions for membership and voting in SACROP**".

6. The assembly of members shall be convened based on an invitation from the board of the association. The invitation must contain:

a/ the name and address of the association,

b/ place, date and time of the assembly of members

c/ the agenda of the assembly of members.

7. The invitation must be sent to the e-mail addresses of the members of the association not later, then 14 days prior to the assembly, and published on the website of the association.

8. The assembly of members also involves the board members of the association and the revision board, who have the right to speak at the assembly of members. For invitation of members of the revision board and the board of directors, apply the same provisions as for inviting regular members of the association.

## **VII. The Board of the association**

1. The board of the association / hereinafter referred to as the board / is the executive body of the association. Its activities are governed by statutes, generally binding regulations, decisions of the assembly of members and the decisions of the revision board.

2. The board is generally made up of five members, appointed and dismissed by the assembly of members. Members of the board elect from among its members one chairman and one vice-chairman of the board, of whom at least one must be one of the founding members of the association within the first three years, and who cannot be removed and replaced by another member if the other founding members of the association disagree. A board member may be elected repeatedly.

3. The term of office of the board members is three years. The dissolution of the office of a member of the board occurs when:

\* expiration of the term,

\* appeal,

\* written resignation of the member of the board, the resignation becomes effective on the date of the meeting of the authority that is authorized to vote on the admission of board members.

4. In the event of the dissolution the function of a member of the board, the other board members are authorized to co-opt a new member of the board. The termination of the function of the co-opted member of the board, apart from the reasons mentioned in the previous paragraph occurs at the moment of the meeting of the authority that is entitled to elect and remove the association board members.

5. The Board of the association mainly:

- a/ manages and secures the operations of the association,
- b/ manages the assets of the association,
- c/ it deals with suggestions and proposals from the association members,
- d/ it prepares and manages the assembly of members,
- e/ it prepares a program of operations of the association, an activity report, the budget draft of the association, an report on the economics and management of the association,
- f/ it informs the revision board and assembly of members of the activities of the association, the management of associations assets etc..,
- g/ accepts new members into the association and maintains a list of association members,
- h/ performs other rights and obligations designated by these statutes, and also generally binding regulations,
- i/ drafting of a work plan and an annual report,
- j/ it proposes the budget and asset management report,
- k/ it proposes an annual membership contribution to the activities of the association,
- l/ it convenes and substantively prepares the deliberation of the supreme body and prepares basic materials for these negotiations and deliberations,
- m/ it proposes the members of the revision board.

6. Members of the Board are the statutory body of the association. On behalf of the association are authorized to act and to sign documents the following: persons mentioned in the paragraph I., paragraph 4., the chairman of the association together with another board member or two members of the board together.

7. The board decides by an absolute majority of its members and shall meet as necessary based on a proposal from the chairman or at least two board members, or at the request of at least three members of the revision board, but at least once every six months.

### **VIII. The revision board**

1. The revision board is the control body of the association.

2. The revision board has three members, who are elected by the assembly of members, based on a proposal from the board of the association. The revision board may contain no more, than one member of the board. The members of the revision board vote from among its members a chairman of the revision board, whose office can be revoked at any time and replaced by another member of the revision board.

3. The term of office for the members of the revision board is three years. The office of the member of the revision board can cease to exist when the following takes place:

- \* expiration of the term of office,
- \* appeal,
- \* written resignation by the member of the revision board, the resignation becomes effective on the date of the meeting of the authority, which is authorized to vote on the admission a member of the revision board into office.

4. In the event of the termination of the office of a member of the revision board, the other members of the revision board shall be entitled to co-opt a new member of the revision board. The termination of the office of the co-opted member of the revision board takes place, when, (apart from those reasons mentioned in the previous paragraph), the meeting of the authority, which is entitled to elect and remove the members of the revision board takes place.

The revision board duties are in particular:

- a/ it monitors the activities of the board of the association as well as other association bodies and offices
- b/ it supervises the compliance with the statutes,
- c/ it oversees the proper implementation of activities undertaken in the framework of the association,
- d/ it has the right to be heard at the meetings of the assembly of members,
- e/ it gives recommendations and instructions to the board,
- f/ it reviews the association, compiles an activity report and a management report,
- g/ it protects and promotes the interests the association,
- h/ it controls the activity of the board of the association,
- i/ it is entitled to request from the board information about association activities, and the management of the association,
- k/ comments on the plan of activities,
- l/ performs other rights and duties assigned by these statutes, or by generally binding regulations.

6. The revision board decides by an absolute majority of its members and shall meet as necessary based on a proposal from the chairman or the board, but at least once a year.

## **IX. Workgroups / Project teams**

1. The Workgroup / project teams provide various professional activities of the association, whose number, scope and focus is determined by the assembly of members.

2. The chairman of the workgroup / project team is proposed and approved by the board. The appointment of a chairman of the workgroup / project team shall be subject to approval by an absolute majority of board members. The term of office of the chairman of a workgroup / project team is three years and it can be approved repeatedly. A member of the board may also be the chairman or a member of a workgroup / project team. A

membership in a workgroup / project team is not necessarily limited to one group / project.

4. Members of the board and the chairman of the workgroup / project team may delegate any member of the association to a particular and clearly specified role of a representative of SACROP. A delegated representative may act in the name of the association, but is not authorized to act on behalf of the association or to sign any agreements alone.

5. Workgroups / project teams may operate in the following areas :

- area of internal affairs, organization of meetings, membership and membership fees
- cooperation and communication with MZ (Ministerstvo zdravotníctva / Ministry of Health), ŠUKL (State Institute for Drug control) , the National Council, EK (Ethics committee), SZU (Slovak Health University), media, health insurance companies, patient organizations, medical facilities , **AIFP** (Asociácia inovatívneho farmaceutického priemyslu / The Association of Innovative Pharmaceutical Industry) a **SARAP** (Slovenská asociácia spoločností v oblasti liekovej regulácie / Slovak Association of Regulatory Affairs Professionals)
- in the area of legislation
- education, code of ethics, compliance with GCP and quality of work of the members of SACROP
- cooperation with similar international organizations and grant programs

The creation, termination and the activities and priorities of the workgroup / project team shall be governed by the current market demand in order to fulfill the purposes and the requirements of the association members.

## **X. The management of the association**

1. The source assets of the Association are membership fees, donations from natural or legal persons, subsidies, grants, income from property and own activities of the civic association.

2. Intellectual property created by the members of the association when working for the association, or carrying out their association related tasks, will remain the property of the association until its demise, or unless the assembly decides otherwise. This does not affect the copyrights of creators of the intellectual property.

3. The association may develop economic activity to achieve income, to ensure that the targets and objectives of the association are met, but it cannot perform entrepreneurial activity for profit.

4. The assets of the association shall be managed in accordance with the principles of sound management.

5. The management and accounting of the association is carried out according to the approved budget in accordance with the applicable laws of the Slovak Republic.

6. The Association may establish alone or jointly with others a company or cooperative, or by other means of equity share establish a stake in the activities of such businesses.

## **XI. Agreements on cooperation**

1. The Association is in line with the relevant legislation authorizing it to conclude agreements on cooperation. The validity of such agreements is determined by their presentation in written form.
2. The cooperation agreement is defining the purpose of cooperation, modalities of its implementation, the rights and obligations of the participating associations and the means of contribution to the cooperation.

## **XII. Dissolution of the association**

1. The Association shall be dissolved when:

a/ members of the assembly decide on the voluntary dissolution of the association or by a merger with another association,

b/ legal decision of the Interior Ministry about its dissolution.

2. After the dissolution of the association a property settlement will take place. The property settlement shall firstly cover all the debts of the association. Remaining assets may be used only in accordance with these statutes.

3. The Board shall appoint a liquidator when the association does not cease to exist by a merger with another public association.

4. The liquidator is to settle all payables and receivables, the liquidation balance is dealt with as per decision of the highest governing body of the association. About the dissolution of the association shall the liquidator notify the Ministry of Interior within 15 days after completion of the process. The liquidation of the association shall follow the provisions described in § 70 -75 of the Commercial Code.

## **X III. Final provisions**

1. These statutes come into effect as per decision of the assembly members from **03.06.2015**.
2. The coming into effect of these statutes means, that the previous statutes, that have been registered with the Ministry of the Interior on the 15.11.2012 with the number **VVS/1-900/90-40365** are repealed.

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**Katarína Renz**  
**Chairwoman of the board**

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**Angelika Schmiedlová**  
**Member of the board**