

Academic Steering Committee

Charter

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Chapter I General Provisions

Article 1 In order to strengthen the construction of clinical study steering committee, improve the management structure of clinical study, and ensure the effective role of experts in ethics, clinical practice, and biostatistics in clinical study, the Charter of Association is formulated in accordance with the relevant guiding principles of ICH-GCP and NMPA and in consideration of the actual situation of clinical study projects.

Article 2 The Academic Steering Committee of Clinical Research (hereinafter referred to as the "Steering Committee") is the highest decision-making body and academic institution of clinical study. It is responsible for promoting science and democracy, ensuring the standard of clinical study decision-making, scientifically organizing, coordinating and exercising the functions and powers of making decisions on major matters of clinical study affairs.

Article 3 All participants in the clinical study must respect and support the independent exercise of functions and powers of the steering committee, and provide necessary conditions for the normal work of the steering committee.

Article 4 The Steering Committee should follow the laws of clinical study under the relevant principles of ICH-GCP and NMPA, and respect the freedom of study and academic equality. Through clinical study to encourage scientific study innovation, promote scientific study development and personnel training, improve the quality of scientific study; To perform their duties fairly, justly and openly; Protect the interests of patients; To ensure that researchers, laboratory personnel, biostatistics, supervision and other study participants play an active role in scientific study and academic affairs, and promote the scientific development of clinical study in China.

Chapter II Organizational Structure

Article 5 Functions of the Steering Committee:

Chairman: 1 person

Vice-chairman: 1 person

Committee member: 3 person

External spokespersons: 1 person

Secretary of Steering Committee: 1 person

Article 6 Members of the steering committee should meet the following requirements:

- (1) Comply with relevant Chinese laws and regulations; Follow the ICH-GCP and NMPA guidelines;
- (2) Respect science; High academic attainments and high academic reputation;
- (3) Correct style of study and rigorous scientific study;
- (4) Fair and upright, strong sense of responsibility;
- (5) They should perform their duties normally.

Article 7 A member of the Steering Committee may be removed or agree to resign after discussion and decision of the plenary meeting of the Steering Committee under any of the following circumstances during his term of office:

- (1) To apply for resignation from the committee on one's own initiative;
- (2) Unable to perform duties due to reasons such as health, age or change of position;
- (3) Being lazy in performing his duties or violating his obligations as a member;
- (4) Violating laws, professional ethics or academic misconduct;
- (5) Unable or unfit to hold the post due to other reasons.

Chapter III Functions and Powers

Article 8 The members of the steering committee should enjoy the following rights:

- (1) Know the information and operation structure related to the clinical study;
- (2) Inquiring relevant parties on study matters;
- (3) Express opinions freely and independently at meetings of the Steering Committee, and to discuss, consider and vote on resolutions;
- (4) Make suggestions on and supervise the work of study Services and other committees, such as the DMC;
- (5) Other rights provided for in the Charter of Association.

Article 9 The members of the steering committee should perform the following obligations:

- (1) Abide by the Constitution, laws and regulations of the country, observe academic norms and strictly observe academic ethics;
- (2) Abide by the Charter of Association of the Steering Committee, adhere to the academic and professional judgment, and justly perform their duties;
- (3) Diligent and due diligence, and actively participate in the meetings of the steering committee and relevant activities; Strictly keep confidential matters, and should not entrust others to participate in the decision-making of the steering committee;
- (4) Other obligations stipulated in the Charter of Association.

Article 10 The main duties of the steering committee are as follows:

- (1) Review Trial Master File (TMF) documents such as clinical study protocol, case report form, informed consent, study medical record, investigator brochure, etc.;
- (2) Nominate and review the Constitution of the Data Monitoring Committee (DMC);
- (3) Deliberate, demonstrate and put forward guiding opinions on clinical study related subject application, platform construction, operation management, etc.
- (4) Review DMC report and Clinical Study Reports(CSR);
- (5) Make suggestions and decisions on clinical study related results declaration, article publication, conference papers, news publicity, etc.;
- (6) Evaluate the AE or SAE associated with the study;
- (7) Other duties assigned by the Charter of Association.

Chapter IV Rules of Procedure

Article 11 Meeting plan:

- (1) Kick-off meeting: The purpose is to familiarize the members of the academic committee with the study project background, work process and their respective responsibilities, and to review and approve the academic committee charter.
 - Start-up meeting time: before the first subject is enrolled in the group.
 - The agenda of the kick-off meeting includes: clarifying responsibilities, discussing and finalizing the constitution of the academic committee; determining the meeting and schedule of the academic committee to be held; other regular transactional work, etc.
- (3) Planned audit/monitor meeting
 - Meeting conditions and frequency: Regularly hold academic committee meetings to conduct event analysis.

- Meeting review content: understand the specific information of each group's baseline characteristics, occurrence of adverse events, etc.
- (4) Unplanned meetings: According to work needs or events trigger, upon the proposal of the chairman or vice-chairman of the steering committee, or a joint proposal of more than 1/3 of the members, a temporary plenary meeting of the steering committee can be convened to discuss and review related matters.

Article 12 A plenary meeting of the Steering Committee should, in principle, be held only when more than two-thirds of the members are present. The meeting should be presided over by the chairman. If the chairman is unable to preside over the meeting for some reason, he may entrust the vice-chairman to preside over the meeting.

Article 13 The chairman of the steering committee may preside over a meeting of directors to discuss the daily work of the steering committee according to the needs of the work. The members of the Council of Directors should be composed of a chairman, vice-chairmen and a secretary.

Article 14 The Steering Committee should adopt the principle of majority rule in matters decided by the minority. Voting on major matters should be approved only with the consent of more than two-thirds of the members attending the meeting.

Article 15 The matters decided by the Steering Committee should generally be voted by secret ballot, or by show of hands or secret ballot at the choice of the moderator according to the nature of the matters. In case of an urgent matter requiring a vote, the voting may be conducted by communication upon the agreement of the meeting of the chairmen of the steering committee.

Article 16 When the Steering Committee deliberates and evaluates matters related to the interests of the members themselves, the relevant members should withdraw. The chairman of the committee should decide whether the withdrawal is necessary.

Chapter V Supplementary Provisions

Article 17 The steering committee is responsible for the interpretation of the Charter of association.

Article 18 The Charter of Association should be promulgated and implemented after deliberation at the first meeting of the Steering Committee.