ATLAS

https://atlas.ncc.go.jp/en/

Bylaws

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ATLAS
ASIAN CLINICAL TRIALS NETWORK FOR CANCERS PROJECT

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Definitions

APO means Asian Partnerships Office in Bangkok

ATLAS HQ means Department of International Clinical Development and Clinical Research Support Office, NCCH. Data management section and section of biostatistics at NCC shall serve as ATLAS Data Center. APO shall be the Operational Office of ATLAS to manage Board meetings and Committee meetings and support local sites management.

Clinical research means medical research that involves people to test new treatments and therapies.

Ethical Committee (EC) means a group of doctors, scientists, advocates, researchers, and members of the community that has been formally designated to review and monitor all research involving humans. EC are in place to provide ethical oversight and to minimize risk to participants.

Good Clinical Practice (GCP) means A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Introduction to Clinical Research (ICRweb) means an e-learning site that provides knowledge required for clinical research, intended not only for medical researchers who conduct clinical research, but also for clinical research coordinators (CRC) and other clinical research professionals who support it, members and secretariat of the ethics review committee, and all those who assist in the administrative work of research. Link: https://www.icrweb.jp/icr_index.php

Operation office of ATLAS means APO.

Article 1: Name and Purpose

1.1: Name

The name of this organization is: the ATLAS: Asian Clinical Trial Network for Cancers.

Hereinafter referred to as “the Group”

1.2: Purpose

The purpose of the Group shall be to contribute to the development of new treatments and research that are aimed at improving survival outcomes and QOL for patients in Asia via conducting high-quality cancer clinical trials and research. The Group shall serve as a platform for international collaboration, enabling investigators, researchers and clinicians in Asia to work with their counterparts in other regions to share knowledge, expertise, and resources. Additionally, the Group shall address the unique cultural, regulatory, and logistical challenges associated with conducting clinical trials in Asia, such as language barriers, complex regulatory environments, and logistical issues related to patient recruitment and retention.

Article 2: Memberships

2.1: Institutional memberships

2.1.1: Full Member Institutions

Full Member Institutions are institutions that meet the following criteria and have been approved for full membership by the Board (refer to Article 4):

i. Experience of conducting industry-sponsored and/or academic cancer clinical research with a focus on patient-centered outcomes and scientific rigor.

ii. Availability of necessary infrastructure and resources to conduct cancer clinical research, including specialized unit or department for clinical trial support, investigational product storage, accredited laboratory and pathological facility, imaging modalities, ethical committee (EC) that is compliance with GCP.

iii. Strong commitment to regulatory compliance and ethics in clinical research, including compliance with GCP guidelines, local regulations, and international ethical standards.

iv. Collaborative and team-oriented approach to cancer clinical research, with a willingness to work with other institutions, researchers, and stakeholders to advance the field.

v. Participating in at least one Group study or providing assurance that the institutions will actively participate in future Group studies.

Full Member Institutions have the following rights and privileges:

i. The right to participate in the Group's activities, including clinical trials and research, committees,

study group, and scientific meetings or events.

ii. The right to access the Group's resources and networks, including databases and research materials under the approval of the Board, and collaborative partnerships.

Full Member Institutions are expected to fulfill the following responsibilities:

i. Adherence to the Group's bylaws and policies, including ethical conduct in all aspects of cancer clinical research.
ii. Regular communication and collaboration with other Full Member Institutions, researchers, and stakeholders to advance the goals and objectives of the Group.
iii. Participation in the Group's activities, including semiannual meeting, clinical trials, committees, and scientific events.
iv. Assigning at least one designated coordinator to manage Full Member and/or Associate Member (refer to 2.2) activities within the institution.

2.1.2: Associate Member Institutions

Associate Member Institutions are institutions that have an interest in cancer clinical research and wish to be involved in the Group's activities and contribute to the Group in any way but do not meet the criteria for Full Membership.

Associate Member Institutions have the following rights and privileges:

i. The right to participate in the Group's activities, including scientific meetings, symposium, and other events organized by the Group.
ii. The opportunity to collaborate with Full Member Institutions, researchers, and stakeholders in cancer clinical research.

Associate Member Institutions are expected to fulfill the following responsibilities:

i. Adherence to the Group's bylaws and policies, including ethical conduct in all aspects of cancer clinical research.
ii. Regular communication and collaboration with other Associate Member Institutions, Full Member Institutions, researchers, and stakeholders to advance the goals and objectives of the Group.

Associate Member Institutions may be invited to provide input and feedback to the Board on an ad-hoc basis.

2.2: Individual memberships

2.2.1: Full Member

Full Members are investigators, physicians, research staff, or other relevant personnel who are affiliated with a Full Member Institution and actively involved in cancer clinical research. No limitation shall be made on the number of members at any Memberships institution. All Full Members must obtain ICR web account and register in the Registration system, with ratification by the Board. Full Members are individuals who are actively involved in cancer clinical research and wish to contribute to the Group's activities.

Eligibility for Individual Full Membership is based on the following criteria:

i. The individual is currently employed or affiliated with a Full Member Institution.
ii. The individual demonstrates a commitment to cancer clinical research through their professional activities, publications, or contributions to the field.
iii. The individual is involved in or has confirmed participation in the Group study that is ongoing or under preparation.
iv. The individual adheres to ethical and regulatory guidelines for clinical research and upholds the principles of integrity, professionalism, and scientific rigor.

Eligible individuals who wish to become full members complete the application form. The completed application form is submitted to the designated coordinator at the Full Member Institution. The coordinator reviews it for completeness and accuracy, ensuring that the applicant meets the eligibility criteria. Upon verification and approval, the coordinator submits the application form to the Board together with the latest list of the Group individual member at the institution.

The Board reviews the application and makes a determination regarding the individual's acceptance as a Full Member.

The decision is communicated to the applicant and the Full Member Institution's coordinator.

2.2.2: Associate Member

An individual investigator, experts, or staff who may not meet the eligibility criteria for Full Members but has an interest in cancer clinical research and contributes to the Group in some way, such as by providing scientific expertise, participating in the Group organized events, collaborating on research projects, or supporting the Group's advocacy efforts.

Individuals wishing to become an Associate Member of the Group must complete and submit an application form to the operational office of the Group.

2.2.3: Special Member

Special Members are scientists or investigators who possess unique expertise or qualifications that are not readily available among the Full Member Institutions of the Group. They may include individuals who have relocated to non-member institutions but wish to maintain their involvement as primary investigator or sub investigator for specific the Group studies. Their role within the Group is at the discretion of the Board and may be subject to review and endorsement by the Board.

Potential Special Members are identified through consultations, recommendations, or other means deemed appropriate by the Board. The Board evaluates the qualifications and contributions of the potential Special Members, considering their expertise, experience, and potential contributions to the Group. If the Board determines that an individual meets the criteria of Special Member, an invitation is extended to the individual to join the Group as a Special Member. Upon acceptance of the invitation, the individual becomes a Special Member.

2.3: Affiliate Organizations

Affiliate Organizations are non-hospitals or non-cancer centers, but organizations or groups that have an interest in cancer research and treatment and wish to contribute to the Group's goals and objectives in some way such as academic oncological society, clinical trial group, or patient advocacy group but do not meet the criteria for Full or Associate Member institutions.

The rights and privileges of Affiliate Organizations shall be determined by the Board and may be subject to periodic review.

Affiliate Organizations may be invited to provide input and feedback to the Board on an ad-hoc basis. The criteria for Affiliate Organizations, including eligibility requirements and the process for applying for Affiliate Organizations, shall be determined by the Board and set forth in the policies and procedures of the Group.

2.4: Termination of Institutional memberships

2.4.1: Full Member Institution

i. A Full Member Institution may resign from the Group by giving written notice to the Board. The resignation will take effect on the date specified in the notice or on the date it is received by the Board.

ii. Failure to enroll at least one patient to the Group studies within a period of two years, unless otherwise waived or extended by the Board.

iii. If, for two consecutive years, no representative from a Full Member Institution is able to participate in the semi-annual meeting, the institution may face termination of its Full Member status.

iv. Expulsion for cause, such as violation of these bylaws or other conduct prejudicial to the interests of the Group, by a two-thirds vote of the Board present and voting at a meeting called for the purpose, and after the member has been given an opportunity to be heard.

2.4.2: Associate Member Institution

i. An Associate Member Institution may resign from the Group by giving written notice to the Board. The resignation will take effect on the date specified in the notice or on the date it is received by Board.

ii. Expulsion for cause, such as violation of these bylaws or other conduct prejudicial to the interests of the Group, by a two-thirds vote of the Board present and voting at a meeting called for the purpose, and after the member has been given an opportunity to be heard.

2.5: Termination of Individual Memberships

2.5.1: Full Member and Associate Member

i. A Full Member and Associate Member may resign from the Group by giving written notice to the Board. The resignation will take effect on the date specified in the notice or on the date it is received by the Board.

ii. Expulsion for cause, such as violation of these bylaws or other conduct prejudicial to the interests of the Group, by a two-thirds vote of the Board present and voting at a meeting called for the purpose, and after the member has been given an opportunity to be heard.

2.5.2: Special Member

i. Special Member may be revoked by the Board if the member engages in conduct that is detrimental to the objectives of the Group or cancer clinical research.

ii. A Special Member may resign from the Group by giving written notice to the Board. The resignation will take effect on the date specified in the notice or on the date it is received by the Board.

iii. Expulsion for cause, such as violation of these bylaws or other conduct prejudicial to the interests of the Group, by a two-thirds vote of the Board present and voting at a meeting called for the purpose, and after the member has been given an opportunity to be heard.

Note: The Board reserves the right to review and approve all membership terminations.

Article 3: Meetings

3.1: Semi Annual Meetings

The Group shall hold semi-annual meetings twice a year. The dates, times, and location of the meetings shall be determined by the operational office of the Group. The semi-annual meetings may be held in-person, online, or hybrid as determined by the operational office.

At least one representative from each Full Member Institution shall attend the semi-annual meetings. If a representative from the institution is unable to attend, an alternate representative may be designated to attend in their place. Other individual members such as Associate or Special members may also attend the semi-annual meetings.

The purpose of the semi-annual meetings shall be to review the progress of ongoing studies or projects, discuss new studies, provide a forum for discussion among members, and so on.

3.2: Special meetings

Special meetings of the Group may be called by the President or by a majority of the Board member. Notice of the time and place of the special meeting shall be given to each member of the Group not less than thirty days before the meeting.

Article 4: Board

4.1: Purpose

The Board of the Group is the governing body responsible for the management and governance of the organization. The Board shall have full authority and responsibility to act on behalf of the Group in all matters related to its mission and goals of the Group.

4.2: Composition

The Board shall consist of the following members:

4.2.1: President:

The President shall serve as the chief executive officer of the Group and provide overall leadership and strategic direction to the organization.

4.2.2: President Elect:

The President elect shall work closely with the President and assume the position of President at the end of their term. They shall support the President in their duties and responsibilities.

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4.2.3: National Principal Investigators (National PIs):

Each collaborative county/region shall appoint two (2) national PIs as a voting member of the Board. National PIs shall be selected from Full Member Institutions where at least one patient is enrolled within two years for any of the Group studies. The process of selecting National PIs to represent each collaborative country is flexible and tailored to individual countries. Collaborative countries designate National PIs and encourage them to set their own criteria for selection. The proposed candidates are reviewed by the ATLAS Board, and final approval is obtained through consensus-building. The representative shall serve as a liaison between the collaborative country and the Group and shall provide input and guidance on matters related to cancer clinical research in the respective country. Representative members shall serve for a term of three (3) years and have no term limit. If a National PI assumes a different position such as a President elect within the Board, a new National PI shall be elected from their country to serve as their replacement.

4.2.4: Committee chairs:

There shall be one (1) Chair from each Committee who shall be responsible for proposals, decisions, and achievements of the Committee. All Committee Chairs may be appointed for three (3) year term and have no term limit. Committee members shall be appointed by the Committee Chair and reported to the Board in accordance with the Group mission and vision. The first Chair shall be appointed by President from an investigator or experts in terms of specific scientific field to which the Committee shall be relevant. The second Chair onwards shall be appointed from Committee members by the former Chair and approved by the Board.

4.2.5: Director of ATLAS HQ:

The Director of the Group HQ shall oversee the daily operations of the Group, manage administrative tasks, and ensure effective coordination among members, study groups and committees.

4.2.6: Study group Chairs:

The purpose of cancer site specific and tumor agnostic Study Group is to propose, develop, and conduct clinical trials and translational research to improve outcomes for cancer patients. There shall be one (1) Chair of Study Group who is PI of the Group studies, nominated by former Chair, and elected by a majority vote of the Study Group members. The Chair shall serve for a term of three (3) years and have no term limit. The first Chair of Study Group shall be appointed by President.

4.2.7: Representative of the top 5 recruiting institutions:

One (1) representative shall be appointed by the top 5 recruiting institutions based on the number of patients enrolled in the Group studies. The representative shall provide input and guidance on matters

related to patient enrollment and recruitment. Roster of five (5) representative investigators shall be renewed every year. If other Board members are already affiliated with one of the top 5 recruiting institutions, an additional representative shall be selected from that institution. This additional representative shall be an investigator or expert from the institution who has demonstrated outstanding contribution to patient enrollment in the Group studies

4.2.8: Elected member:

Elected members shall serve as non-voting members. Elected members shall actively participate in discussion and provide constructive advice to other Board members. Nominations of Elected members are handled by the Group HQ and APO. APO must receive either of the followings in order to place nominated investigators or experts who are relevant to the Group activities on Board.

1. Approval from PI of the Group collaborative trials
2. Approval from appropriate Committee Chair, Study Group Chair, or Director of the Group HQ

4.3: Voting member

Voting Members of the Board refer to individuals holding active membership status and possess the privilege to cast votes during official meetings and decision-making processes.

The following positions within the Board hold voting membership status:

- President
- President Elect
- National Principal Investigators (National PIs)
- Committee Chairs
- Director of ATLAS HQ
- Study group Chairs
- Representative of the Top 5 recruiting institutions

Voting Members are required to cast their votes on various matters, including but not limited to:

- Approval of new studies and research proposals
- Amendments to the ATLAS Bylaws and organizational guidelines
- Key strategic decisions for ATLAS's growth and collaboration
- Selection of individuals for leadership roles within ATLAS

4.4: Eligibility

Board members shall be affiliated with a Full Member Institution of the Group. They should be investigators, research staff, or representatives from Full Member Institutions who actively contribute

to the mission and objectives of the Group.

4.5: Election

The President Elect shall be the only position elected by the Board. The election of the President Elect follows a thorough and transparent process. The Board announces the upcoming election and invites Full Member Institutions to nominate candidates (self-nomination allowed). Nomination forms, along with the candidates' curriculum vitae (CV), are submitted to the Nominating Committee composed of the current President, past Presidents, and the Director of the Group HQ. The committee carefully reviews the nominations and proposes one or more candidates based on their qualifications and suitability. During a Board meeting, the proposed candidates are presented, and Board members vote to select the President Elect. The candidate receiving the majority vote is elected to the position, ensuring a fair and democratic process in choosing the next leader of the Group.

4.6: Voting Procedure

The Board shall conduct its business by vote of a majority of its members present, provided that a quorum is present.

4.7: Quorum

A quorum shall consist of at least fifty percent (50%) of the Board members.

4.8: Resignation, Removal, Death or Disability of Board members

4.8.1: President

In the event of the resignation, removal or death of President, President Elect shall immediately assume the position to serve as new President for the remainder of the unexpired term of the former President. Additionally, the President Elect shall continue to serve for the defined term as President. For example, if the President resigns 1.5 years into their term, the President Elect will assume the role of President immediately and serve for the remaining 0.5 years of the unexpired term, as well as serve the defined term (2 years) as President. Nominating committee shall appoint one candidate of the next President Elect. The Board shall perform special voting on the proposed candidate for the position of President Elect.

4.8.2: President Elect

In the event of the resignation, removal or death of President Elect, Nominating committee shall appoint one or more candidate of the next President Elect, considering nominations from Full Member Institutions. The Board shall perform special voting on the proposed candidates for the position of President Elect.

4.8.3: National PIs

In the event of the resignation, removal or death of National PIs from each collaborative country, the country's remaining member whose National PI has resigned, been removed, or died shall appoint another physician to serve as a new National PI from the country for the remainder of the unexpired term. The new National PI shall be approved by the Board.

4.8.4: Chair of Study Group, or Committee

In the event of the resignation, removal or death of a Chair of Study Group or Committee, the members of Study Group, or Committee whose Chair has resigned, been removed, or died shall appoint another physician to serve as a new chair for the remainder of the unexpired term. The new Chairs shall be approved by the Board.

4.8.5: Removal

A Board member may be removed by a two-thirds majority vote of the Board member.
Any Board member who has not attended three consecutive Board meetings without prior notification to the President or Director of the Group HQ may be removed from the Board. The President or Director of the Group HQ will notify the Board member in question of their removal and the reasons for it, and the Board will vote on the removal at its next meeting. A simple majority vote of the Board is required for the removal to take effect. The vacancy created by the removal of a Board member may be filled by the procedure outlined in 4.7 of this Article.

Article 5: Committees

5.1: Establishment of Committees

The Board may establish committees as necessary to carry out the purposes of the Group. Any
Full Member can apply to establish a new committee by submission of an application form to the Board for approval. The proposal shall include the proposed committee's purpose, membership, and proposed activities. The Board shall review and approve the proposal by a simple majority vote at a Board meeting.

5.2: Committee Membership

The Board shall approve committee chairs and members. Committee members may be individuals from Full Member Institutions or Special Members of the Group. Committee chairs shall be chosen from committee members.

5.3: Committee Meetings

Committees shall meet at the call of the committee chair, at least once per year. Committee meetings may be conducted in person, by telephone, or by electronic means.

5.4: Committee Reports

Committees shall report to the Board at each Board meeting. The committee chair shall provide a written report on the activities and progress of the committee at the end of the year.

5.5: Committee Dissolution

The Board may dissolve a committee at any time by a simple majority vote at a Board meeting. Committees may also be dissolved if they have not met for more than one year without good cause, or if their purpose is no longer relevant to the Group activities.

Article 6: Study Group

6.1: Establishment of Study Group

The Board may establish Study Group as necessary to identify a specific scientific area of cancer research. Any Full Member can apply to establish a new Study Group by submission of an application form to the Board for approval. The proposal shall include the proposed Study Group's purpose, membership, expected impact, and proposed activities. The Board shall review and approve the proposal by a simple majority vote at a Board meeting.

6.2: Study Group Memberships

Study Group membership shall be open to Full Members from Full Member Institutions, as well as Special Members who possess special expertise or relevant experience, as determined by the Board. Full Member Institutions may nominate investigators or research staff from their institutions to participate in specific Study Groups. Special Members may be invited to join Study Groups based on their unique contributions and knowledge.

6.3: Study Group Meetings

Study Groups shall hold regular meetings to discuss research progress, share findings, and collaborate on clinical research activities. The frequency and format of Study Group meetings shall be determined by the Study Group Chairs, in consultation with the Board.

6.4: Study Group Reports

Study Group Chairs shall provide periodic reports to the Board on the activities, progress, and findings

of their respective Study Groups. These reports shall include updates on ongoing clinical trials, research outcomes, and any other pertinent information related to the Study Group's focus area.

6.5: Study Group Dissolution

The Board reserves the right to dissolve a Study Group if it is deemed necessary or in the best interest of the Group. The dissolution of a Study Group shall be initiated by the Board and require a majority vote during a Board meeting. Upon dissolution, the Study Group Chairs shall finalize and submit a final report summarizing the Group's activities and outcomes to the Board.

Article 7: Officers

7.1: President

President shall have the primary responsibility for the development of overall research strategy, collaborative activities within the Group, and all key components related to the conduct of approved clinical trials. President shall serve on various committees: as set forth herein; shall receive and act on the recommendations pertaining to any Group activities, scientific operations and structure from committee; shall make final decisions about the prioritization of protocols and selection of clinical studies. President shall be under 65 years old when he/she is appointed. The President shall serve a term of two (2) years. In principle, re-election is not allowed. President's term commences on the date of endorsement by the Group Board.

7.2: President Elect

Nominating committee shall appoint at least one candidate of next President at the same timing of President Election, considering nominations from Full Member Institutions. Voting members of the Board shall vote for one President Elect. President Elect shall serve together with President and accumulate experiences as next President. President Elect shall be under 65 years old when he/she is appointed and elected from the country that is different from current President's home country. The President Elect shall serve a term of two (2) years and automatically assume the position of President at the end of the President's term. In principle, re-election is not allowed. President Elect's term commences on the date of endorsement by the Board.

7.3: Director of ATLAS HQ

The Director of ATLAS HQ shall be responsible for the day-to-day operations of ATLAS HQ. Director of ATLAS HQ has no term limit.

Article 8: Approval and Amendment of Bylaws

8.1: Approval of Bylaws

The initial approval of the bylaws shall be conducted by the Board. The proposed bylaws shall be distributed to all Board members for review and consideration. A formal vote shall be held during a scheduled Board meeting, requiring a majority vote in favor of approval for the bylaws to be accepted.

8.2: Amendment of Bylaws

Amendments to the bylaws may be proposed by any Board member or by a designated committee responsible for overseeing bylaw revisions. Proposed amendments shall be submitted in writing to the Board and distributed to all Board members for review and consideration.

8.3: Review and Discussion

The proposed amendments shall be reviewed and discussed during a scheduled Board meeting or through electronic means of communication. Board members shall have the opportunity to provide feedback, raise questions, and engage in a thorough discussion regarding the proposed amendments.

8.4: Voting on Amendments

Following the review and discussion phase, a formal vote on the proposed amendments shall be conducted. The voting process may take place during a scheduled Board meeting or through electronic means of voting. A majority vote in favor of the proposed amendments is required for their approval and incorporation into the bylaws.

8.5: Documentation of Amendments

All approved amendments shall be properly documented and recorded within the official bylaws document. The amended sections or provisions shall be clearly marked to indicate the changes made, including the date of the amendment.

8.6: Distribution of Amended Bylaws

The updated bylaws, including any approved amendments, shall be promptly communicated to all relevant parties, such as Board members, the Group members, and other stakeholders. The amended bylaws shall serve as the governing document for the Group and shall supersede any conflicting provisions in previous versions.

ATLAS
ASIAN CLINICAL TRIALS NETWORK FOR CANCERS PROJECT

Structure of ATLAS