



Draft v. October 2015
Submitted to Exec. BoD : Oct.2015
Approved: Nov.10, 2015

POLICY DOCUMENT

Membership Committee of the Gynecologic Cancer InterGroup

Composition

The Membership Committee consists of the immediate three past Chairs of the GCIG plus the Operations Manager (ex-officio), current GCIG Chair and Chair-elect and those members of the Executive Committee as appointed by the BoD.

The Membership Committee as a whole can be dissolved at any time by the GCIG Executive-Board of Directors.

The Membership Committee on behalf of the Executive-Board of Directors agrees to enforce the rules formulated and agreed upon by the General Assembly concerning membership.

Terms of Reference

The Membership Committee is responsible to the Executive-Board of Directors. The role of Committee is to implement the rules related to membership of the GCIG including potential new member applicants, provisional members, full members, industry partners, governmental/regulatory authority members and Liaison groups. The Membership Committee may consider multiple applications from a single country provided that the overall participation of that country in the activities of the GCIG is not negatively impacted and that the existing member groups of GCIG are not negatively impacted.

The Membership Committee will develop and formalize, in collaboration with the Executive-Board of Directors, a review process for the application of new candidate groups for provisional membership with the GCIG and also the re-evaluation of such provisional members for full membership.

The Membership Committee will also monitor the participation of full members in GCIG activities. These review processes will comply with the statutes of the GCIG.

Procedures

A full member of the GCIG is a cooperative clinical research group focused on the successful conduct of trials in the population of women affected by gynecologic cancer. Each member group will provide the Operations Manager of the GCIG with the name of a Contact

Representative (or contact person) who will be the liaison between that specific group and the GCIG for matters such as dues payments, administrative issues and membership status.

- *Full Members*

A full member is a cooperative clinical trials group and not an individual person nor a single institution. Full Members are expected to contribute actively in the GCIG, i.e. at least participate in one of the GCIG intergroup trials. Full member groups may appoint up to six representatives to attend GCIG meetings, i.e. 3 principal representatives, 1 statistician, 1 operational/data manager and 1 representative for translational research. Each Member Group will have 1 voting representative on the Executive-Board of Directors; they may lead a GCIG trial and can apply for executive positions when appropriate.

Full Member groups will be reviewed by the Membership Committee every 2 years after receiving their full membership status to ensure that:

- 1) the member group has actively participated in at least one GCIG study during the past five years, as reflected by accrual or contribution to at least one GCIG clinical trial AND by participation in at least one publication; and
- 2) the member group has been represented by at least one representative each year; and, has been represented by at least one Harmonization representative (Ops/Stats) at least once per calendar year; and
- 3) the member group has provided evidence that it has complied with all trial criteria for GCP in the trials in which the group has participated; and, met GCIG QA criteria (safety reporting, indemnity/insurance, monitoring/auditing, RT QA, etc); and
- 4) the member group has paid annual dues; and
- 5) the member group complies appropriately with the Statutes and Bylaws of the GCIG

The Executive-Board of Directors has the right to exclude a full member in the case that the member group did not adhere to the GCIG statutes and bylaws. In the case of an unsatisfactory biennial review, the Membership Committee will first recommend to the Executive Board that such a member be advised that they will be considered as a *Probationary Member* for one year from that time. After one year, failure to comply with the requirements of membership during that time will lead to the Membership Committee recommending to the Executive Board that the Member Group be notified that their membership has been terminated.

- *Provisional Members*

Any multicenter, cooperative clinical trials group (i.e. a research group conducting clinical trials in the population of women affected by gynecologic cancer at the time of submission) can apply for provisional membership if:

1. it has or is able to perform clinical trials in gynecologic cancer(s) under GCP conditions , with sufficient data management and statistical support; **and**
2. it has completed and published in the peer-reviewed literature at least one clinical trial in the field of gynecologic oncology in the last five years, **and**
- 3) it is willing to support attendance of its representatives at the meetings of the General Assembly of the GCIG twice yearly with representation and active participation in the Standing Committees and working groups; **and**
- 4) it is committed to pay annual dues; **and**
- 5) it agrees to comply with GCP ; and, meets the GCIG QA criteria (safety reporting, indemnity/insurance, monitoring/auditing, etc); **and**
- 6) it is committed to support attendance at GCIG meetings of at least one Harmonization (Ops/Stats) representative at least once per calendar year;

After review and approval of application, a new member group is admitted as a Provisional Member of the GCIG for a period not to exceed two years. Representation during that two-year period is the same as for Full Members (see below). Each dues-paying provisional and full member group has one vote on the Executive-Board of Directors. Provisional membership may change over to full membership after two years if the criteria for full membership are met. Groups that fail to achieve full membership after the two year provisional period may be considered for repeat provisional membership at a future date on a case-by-case basis.

- *Observer Status*

In the event that the application for Provisional Membership does not comply with all the requested criteria, the GCIG Executive Board can allow Observer Status for that cooperative research group. During that time *one* representative can attend the GCIG open General Assembly and meeting once at their own expense. Thereafter, the group must apply for membership. If unable to meet the requirements for proposed Membership at that time, an extension of another one year may be made providing there is evidence of progress of the observer group in meeting the criteria for membership. However, Observers will have no representation on the Executive-Board of Directors, no voting rights and no annual dues. Groups with Observer Status can only enter patients in GCIG trials as affiliates of a GCIG member group.

- *Industry membership (within the Industry Partner Program)*

GCIG member groups may recommend Biotech/Pharma partners. A recommendation may be made if the following criteria are fulfilled:

- 1) The Biotech/Pharma company has an expressed commitment to advance new knowledge in the domain of clinical trials in the population of women affected by gynecologic cancer

- 2) The Biotech/Pharma company has the appropriate infrastructure to be a partner in a clinical trial project or a translational research project;
- 3) The Biotech/Pharma company expresses their willingness to financially support randomized clinical trials;
- 4) The Biotech/Pharma company agrees to pay annual dues.

If approved by the Membership Committee, the international head office of the industry partner will receive an invitation from the GCIG chair to join the GCIG and to send no more than two representatives to the open meetings (Working Group(s) and General Assembly) and social events. Dues must be paid before attending the meetings. The Industry Partner Program will be evaluated each year by the Executive-Board of Directors, at which time further collaboration will be decided. This is done in collaboration with the Industry Partners.

- *Governmental/Regulatory Authority membership* (within the Clinical trials Sponsorship Program for governmental organizations or non-governmental organizations which provide support to one or more GCIG member groups)

GCIG member groups may recommend Government or National Regulatory Authorities as Government partners Members. If approved by the Membership Committee, the national head office of that partner will receive an invitation from the GCIG chair to join the GCIG and send no more than six representatives to the open meetings (Working Group(s) and General Assembly) and social events. Annual dues (or services in lieu) need to be paid prior to attendance at the meetings. These sponsor partners will be evaluated by the Executive-Board of Directors on an annual basis.

- *Probationary Status*

In those unusual circumstances in which the biennial review of the full member groups identifies that a member group is not fully compliant with the criteria for full membership, that group may be provided with “Probationary Status” for one year. The expectation is that this member group would have 12 months in which to demonstrate satisfactory achievement of all criteria. If after review by the Membership Committee, this compliance is confirmed then the group can be appointed as full members. If compliance is still not in place after this one year, membership in the GCIG for that member group is terminated. This action would be recommended by the Membership Committee to the Executive Board of Directors.

Functioning of the Membership Committee

The members of the Membership Committee may communicate by e-mail or telephone. The Membership Committee will evaluate each application according to the criteria outlined above and report to the Executive-Board of Directors. Membership status of all the provisional and full member groups of GCIG will be evaluated biennially and reported to the Executive-Board of Directors in writing.

All decisions concerning the membership status by the Membership Committee will be by *recommendation* to the Executive-Board of Directors, who will determine the final decision.

FURTHER COMPLEMENTARY DETAILS AND INFORMATION MAY BE FOUND IN THE GCIG BYLAWS AND SOPS.

