



BIG-02.5

General Assembly/Member Groups Charter

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Contents

1. INTRODUCTION.....	3
2. SCOPE.....	3
3. OBJECTIVES.....	3
4. ROLE AND RESPONSIBILITIES.....	3
5. COMPOSITION AND STRUCTURE.....	3
6. MEETINGS AND RELATED PROCEDURES.....	4
6.1 Meetings.....	4
6.2 Quorum and voting.....	4
6.3 Agenda and Minutes.....	4
7. EXPECTATIONS.....	5
7.1 General terms.....	5
7.2 Scientific Meetings.....	6
7.3 Presentation of trial ideas at BIG meetings.....	6
7.4 Participation in Task Forces or Working Groups.....	6
7.5 Participation in BIG studies.....	6
7.6 Attendance at BIG meetings.....	7
7.7 BIG-NCTN Annual meetings.....	7
7.8 BIG travel policy.....	7
7.9 Confidentiality and intellectual property rights.....	7
8. EVALUATION OF MEMBERSHIP.....	8
9. INTERNAL REFERENCES.....	8

1. Introduction

The General Assembly (GA) comprises all BIG Member Groups and serves as the highest authority with respect to overall direction of BIG. The purpose of this Charter is to formalize the objectives, role, and responsibilities of the GA, as well as to define the

- Composition and structure
- Meetings and related procedures
- Expectations of BIG Member Groups
- Membership evaluation.

2. Scope

This charter applies to all BIG Member Groups, whether Effective or Adherent Members (see section 7).

3. Objectives

The main objectives of the GA are to:

- promote and facilitate the development of international breast cancer research through collaboration
- help BIG achieve its strategic goals
- protect and balance the interests of all stakeholders and uphold the BIG principles of research conduct
- enhance international collaboration beyond the BIG network.

4. Role and responsibilities

The GA is the highest authority with respect to overall direction of the association. To this end, the GA:

- approves the main orientations and future strategies
- approves BIG's annual budgets and accounts
- approves new member groups and the termination of membership
- approves any modifications to the statutes
- serves as the pool from which candidates to the Executive Board (EB) are proposed and fills half of any available EB seats by direct vote from among those candidates
- in case dismissal is proposed of an EB member who has been elected by the GA, endorses (or not) that decision
- approves the dissolution of the Association when such dissolution is voluntary.

5. Composition and structure

The GA is composed of all BIG Member Groups of the association, which may be either Effective or Adherent Members. Effective Member groups are those that meet the criteria of being legal entities that conduct clinical trials and other research in breast cancer. Groups accepted to BIG as Adherent Members have all the same rights as

Effective Member groups, except to nominate candidates to the BIG EB and to vote. Reasons for accepting a group as an Adherent Member include 1) not yet being a legal entity (with the expectation that it will become one) and 2) not yet having had experience in breast cancer clinical trials.

Each Member Group must assign one person to be its official representative. Alternatively, to facilitate attendance at meetings and engagement in BIG activities, two individuals may be chosen as “co-official” representatives, with the understanding that it has only one vote (provided that it is an Effective Member). The duration of GA membership is linked to the approval and continuation of the membership of the group according to the criteria set out in sections 7-8.

6. Meetings and related procedures

6.1 Meetings

Ordinary GA meetings shall be held face-to-face at least once per calendar year on a date proposed by the EB, generally at a major oncology conference that a majority of BIG members attend (e.g., ASCO). Such meetings may also be held virtually for compelling reasons. Extraordinary GA meetings, virtually or in person, may be convened by the EB whenever necessary and whenever the interests of BIG so require, either upon the initiative of the EB, or upon request of at least half of the Member Groups. BIG Headquarters (HQ) shall be represented at the GA meetings by one or more representatives without participating in the votes.

6.2 Quorum and voting

Decisions of the GA shall be validly taken when at least one-half of all Member Groups are present or represented. Each Effective Member group has one vote in the GA. Adherent Member groups do not vote but may participate in all discussions around such vote.

Voting can take various forms (e.g., by raising hands, by paper ballot, electronic survey, or other means), depending on the nature of the issue at hand. Resolutions are passed by a simple majority of votes of the Effective Member groups present or represented.

Proposals for modification of the Articles of Incorporation (statutes) or for dissolution of the Association must be made by the EB or by at least two-thirds of BIG’s Effective Member groups. Any such proposals must also be approved by at least a two-thirds majority vote or, in the case of proposed changes to article 4 of the statutes (BIG’s purpose), a four-fifths majority vote is required.

6.3 Agenda and Minutes

A meeting agenda is drafted by the BIG HQ CEO, in consultation with the BIG EB, and is circulated together with any background documents to the participants, approximately 1 month prior to the meeting.

Minutes are prepared by BIG HQ staff members attending the meeting, as designated in advance. Within 15 working days of the meeting, draft minutes are circulated to the meeting participants, who are expected to provide comments/ amendments within 15 working days.

Final minutes, which require confirmation of approval at the subsequent GA meeting, are signed by the Chair and by the Vice-Chair if applicable or Treasurer (or another board member if only one officer was present and if the EB has already approved the document). The minutes are filed at BIG HQ and saved to the BIG members-only section of the website, together with presentations and background documents from the meeting.

7. Expectations

7.1 General terms

Effective Member groups, as represented by their (co)-official representative(s) and any other individuals from the groups participating in BIG activities, must adhere to and support BIG's mission and principles of research conduct (Policy BIG-01); they are also expected to respect BIG's code of conduct (Policy BIG-19) when conducting business under the BIG umbrella.

The responsibilities of the person(s) assigned by an Effective Member group as its (co)-official representative(s) on the GA include, but are not restricted to, the following:

- serves as the main contact between the BIG HQ and the Member Group in general
- attends all the GA meetings or appoints a substitute, which, in order of preference, will be a representative from the same Member Group, a representative from another Effective Member group, or representation by proxy to the Chief Executive Officer
- attends most of the scientific meetings
- registers for the meetings the group attends, per the instructions provided by BIG HQ
- ensures that the group participates in surveys initiated by BIG HQ (e.g., for interest in studies, about satisfaction within BIG, communications or other issues requiring group input)
- keeps its investigators and staff within the group informed about BIG activities.

Adherent Members, as represented by their official representative, also must adhere to and support BIG's mission and principles of research conduct (Policy BIG-01) and are expected to respect BIG's code of conduct (Policy BIG-19) when conducting business under the BIG umbrella. They have the same responsibilities as outlined above for Effective Members, but do not participate in votes.

It should be noted that both Effective and Adherent Member groups must have the legal form of a non-profit association. If this is not possible under the laws and regulations of a member's country or for other reasons, the Member Group must be able to demonstrate that no activity carried out under the auspices of BIG is intended to generate any profit and that, should such profit be generated, the group must demonstrate that such profit will be reinvested in clinical trials or other research in the field of breast cancer carried out by the group.

If a group's legal status changes from non-profit to profit-making, this must be communicated immediately to the BIG EB via BIG HQ. To retain membership, the

reasons for the change must be explained and assurance must be provided that the use of any profit coming activity within BIG complies with the requirements outlined above.

7.2 Scientific Meetings

Scientific meetings are held usually twice per year, in conjunction with major (breast) cancer conferences, the purpose of which is to discuss new and/or recent study proposals, and any other relevant issues. These meetings may be attended by both (co)-official and other representatives of BIG Member Groups. Groups are contacted about two months in advance of a meeting with a formal invitation and a request to register as well as to indicate if they wish to present a study concept for consideration as a BIG study (NB. all such study proposals must first be approved by the BIG EB prior to presentation).

7.3 Presentation of trial ideas at BIG meetings

Each Member Group may present study concepts at BIG Scientific or (time-permitting) GA meetings for consideration/development into a BIG trial, after approval by the EB. Once a study concept has been presented, and if from the discussion at a BIG scientific meeting it appears that there may be interest from other groups, BIG HQ will conduct a survey of Member Groups to confirm interest. If a study concept is presented at a BIG meeting, the Member Group presenting it does so with the intention that the study will become a study under the BIG umbrella. This group may decide which trial model it wishes to use (in particular Supporter or Co-Lead) (Policy BIG-08), which will determine the degree of involvement of BIG HQ in the trial; nevertheless, BIG HQ / the EB have a say in the final decision, bearing in mind BIG HQ workload and other considerations. It is important to note that it is not appropriate for a Member Group to present a study at a BIG meeting for the purposes of identifying potential collaborators and then to run the study outside of BIG. Such activity can lead to sanctions against the group.

Important note: BIG Group members may share a study idea with the EB for eventual consideration by the network at any time of the year regardless of the timing of the Scientific or GA meetings. Depending on the concept and the time between the EB approval and a next meeting, the decision may be taken to conduct a survey without prior scientific / GA meeting discussion. Study concepts should be sent to the BIG CEO (ceo@bigagainstbc.org).

7.4 Participation in Task Forces or Working Groups

From time to time, the EB may decide to issue calls for Member Groups to nominate individuals with specific expertise to participate in a task force or working group dedicated to exploring a particular topic. All Member Groups are welcome to make nominations, and the final composition will depend on the actual activity being proposed and a fair balance of needed expertise, geographical and group representation.

The individuals assigned to participate in a working group or task force may be asked to disclose interests that are potential or actual conflicts of interest, or that may be perceived as such according to BIG's conflict of interest policy (BIG-03).

7.5 Participation in BIG studies

The countries in which a study will take place is a sponsor (pharmaceutical or academic) decision and depends on financial and other considerations, and thus

interest surveys are distributed to Member Groups on a trial-by-trial basis according to their country coverage. Member Groups who fall outside of the geographic area targeted by a trial sponsor will be informed. Because of this situation Member Groups may not be able to participate in all the trials in which they are interested, although the EB and BIG HQ always advocate for maximum country inclusion, especially in studies with pharmaceutical sponsors.

Because of the sponsor's role in determining which countries are included or not in a study, Member Groups are not evaluated according to the number of trials in which they participate.

7.6 Attendance at BIG meetings

BIG members are expected to try to attend BIG Scientific and GA meetings, whether face-to-face or virtual. For GA meetings, a quorum of participation (50%) must be met. BIG Member Groups are expected to register in a timely manner to attend BIG meetings when the invitations are issued by BIG HQ, or to respond to decline (and/ or assign a proxy in the case of a GA) when it is not possible.

7.7 BIG-NCTN Annual meetings

BIG and the U.S. National Cancer Institute's (NCI) National Cancer Trials Network (NCTN) have been holding annual brainstorming meetings since 2005. These events are supported by the Breast Cancer Research Foundation (BCRF) and organized by a BIG-NCTN "Coordinating Committee", consisting of two or more members from the BIG EB, members from NABCG leadership, representation from the NCI, and representatives from BCRF. Each year the Coordinating Committee determines a main theme for the meeting and appoints co-chairs who are experts in the domain (one from the BIG network, one from the North American network). To keep meeting costs manageable when held face-to-face, the BIG-NCTN Coordinating Committee limits participation in the meeting each year to a maximum of about 60 participants in total, with half designated by BIG, and half from NCTN. For virtual meetings the number of attendees may be larger.

On the BIG side, the only "fixed" invitees are members of the BIG EB, any BIG-designated co-chairs of active working groups, and the few BIG HQ physicians / scientists who support the collaboration. Consequently, except for the "fixed" invitees, the invitation list is based on expertise related to the meeting topics and changes from year to year. Being invited one year does not imply an automatic invitation for the next year.

7.8 BIG travel policy

BIG does not have the resources to support the travel of BIG members to BIG Scientific and GA meetings but organizes these either virtually or to take place at congresses that many BIG members attend anyway, and for which members usually find support through their institutions or other sources. However, when BIG members are invited to participate in a face-to-face meeting outside such events, such as ad hoc face-to-face meetings for a working group or task force, BIG will reimburse incurred expenses, as long as they are in line with the principles and procedures outlined in BIG's travel and expenses policy (BIG-04).

7.9 Confidentiality and intellectual property rights

As a general principle, all topics discussed at BIG Scientific and GA meetings are confidential and indicated as such, as are meeting minutes and many other communications / documents circulated by BIG HQ and marked as confidential.

Moreover, study concepts presented at BIG meetings by a group are that group's intellectual property, unless clearly expressed otherwise. What is meant by this is that BIG meetings may not be used by attendees to unfairly "acquire" and implement the ideas of others. Member Groups are also invited to sign a master confidentiality agreement with BIG. Signing this document facilitates the exchange of study synopses, for example, and, in most cases, avoids the need to sign a new confidentiality agreement each time.

8. Evaluation of membership

BIG HQ tracks the presence of Member Groups in meetings, and also whether groups are responsive to requests and surveys issued by BIG HQ. Absences from GA and scientific meetings in combination with no reactions/replies to messages from the HQ / EB in any three-year period constitute grounds for review and eventual revocation of membership of an individual Member Group. If there is a concern and BIG HQ has not been successful in contacting the Member Group:

- BIG HQ informs the EB if a Member Group is subject to reconsideration of membership, according to the above;
- the EB Chair (or other EB member if so, delegated by the Chair) contacts the Member Group's official representative in an effort to identify reasons for lack of attendance/reaction to communications from BIG HQ;
- following the EB Chair's / EB member's consultation, the EB has the authority to formulate recommendations that will be submitted to the GA for discussion / approval.

Other reasons for revoking membership would include acting in ways inconsistent with the legal requirements governing clinical trials, the requirements of BIG's statutes or BIG's Code of Conduct.

However, every effort will be undertaken by BIG HQ and the BIG EB to understand the situation prior to recommending to the GA that membership should be revoked.

9. Internal references

Policy BIG-01 "BIG Mission and Principles of Research Conduct"

Policy BIG-03 "Conflict of Interest and Financial Disclosure"

Policy BIG-04 "Travel and Expenses Policy"

Policy BIG-08 "BIG Study Models"

Policy BIG-19 "Code of Conduct"