Governance Manual

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1. Governance

1.1 Background on governance bodies and documents (Policy BIG-02)

Executive Board
The EB leads BIG as an association and has the authority to take decisions in all areas except those that are reserved for the General Assembly; it is the main scientific and decision-making authority, and ensures the legal compliance and accountability of BIG. The EB is composed of 15 individuals, all with voting rights, except in years when there is a Chair-elect or Past-Chair, in which case there are 16 with voting rights. BIG has adopted a Charter for the Executive Board, formalizing the function and responsibilities of the Executive Board.

General Assembly
The General Assembly (GA) consists of the BIG member groups embodied by their voting representatives, and serves as the highest authority with respect to the overall direction of the association. Each Effective Member Group has one vote. Adherent Member Groups do not vote, but may participate in meetings and discussions. BIG has adopted a Charter for the General Assembly/Member Groups, formalizing the function and responsibilities of the General Assembly/Member Groups.

BIG Headquarters
Working on behalf of the EB and the GA to move BIG’s research agenda forward is the association’s headquarters (BIG HQ), located in Brussels, Belgium. BIG HQ have one voting seat on the EB, manage BIG as an association and support or coordinate BIG’s clinical trials and research programmes. The office is managed by a Chief Executive Officer (CEO), with legal accountability, who oversees all HQ activities.

Articles of Incorporation
The BIG Articles of Incorporation (“statutes”), constitute a legal document, approved by the Belgian legal authorities and relate to the purpose and structure of BIG, in particular membership, and the composition and competencies of BIG’s governing bodies.

Charters
BIG Charters are the governance documents that detail, also in practical terms, the roles and responsibilities of the Executive Board, the BIG Chair, the General Assembly/Member Groups and others (e.g., Advisors, Immediate Past Chair) as the case may be.

At BIG Headquarters, staff and consultants are bound by legal contracts rather than charters, and must also adhere to policies, Standard Operating Procedures (SOPs) and guidelines.

Policies, SOPs and Guidelines
Policies describe the high-level principles adopted by BIG as a network and/or at BIG HQ related to the various aspects of research conducted by BIG. Policies that apply to the entire BIG network must be approved by the BIG Executive Board and the General Assembly.

SOPs and Guidelines describe how an activity at BIG HQ must be performed or provide recommendations how to perform an activity, in order to ensure standardization.

BIG Member Groups work under their own SOPs.
1.2 Executive Board charter

1.2.1 Role and Responsibilities
The EB is the main scientific and decision making authority, in all areas except those that are reserved for the General Assembly, and the EB members are expected to commit considerable time and effort to the Association (see Section 1.2.4).

The EB is primarily responsible for:
- defining and executing BIG’s strategy and strategic aims, presenting them to the General Assembly, and overseeing their execution
- taking scientific and other decisions on issues that fall within the approved strategies and projects
- acting in the best interests of BIG to protect BIG’s reputation while ensuring the legal compliance and accountability of BIG
- regularly evaluating BIG’s mission, vision, and values
- ensuring the integrity of BIG’s research according to BIG’s principles of research conduct (POL BIG-01)
- regularly reviewing BIG’s governance and succession planning, including its own performance and that of the CEO
- reviewing and managing risks as well as conflicts of interest
- ensuring BIG’s financial viability
- providing concrete recommendations, advice and guidance to the General Assembly about financial and other matters
- treating member groups fairly and strive to achieve equitable access to research conducted under the BIG umbrella;
- representing BIG in the wider breast cancer research arena
- taking decisions in areas where the General Assembly does not have exclusive authority, e.g., electing EB officers; succession planning; delegating special powers to one or more persons in the service of BIG (including appointing and/or dismissing and evaluating the CEO);
- providing guidance for work at the BIG Headquarters
- appointing or dismissing Advisors to BIG in the form of working groups, task forces or specially designated functions for individuals, and determining the responsibilities and mandate of those Advisors.

1.2.2 Composition and structure
The EB is composed of 15 individuals, all with voting rights, except in years when there is a Chair-elect or Past-Chair, in which case there are 16 with voting rights. Beginning in 2017, half of all new members are being elected by the General Assembly, and half are appointed by the existing board members.

The EB elects three officers from amongst its members: a Chair, Vice-Chair and Treasurer, and may propose a chair-elect.

Members on the EB have a mandate of 4 years, with 1 possible consecutive renewal, except if the General Assembly has, with two-thirds majority support, decided to allow one or more EB members to be eligible to extend their mandates, in the interest of providing continuity and stability to the association.

Members who resign or are dismissed shall be replaced a time determined by the EB. Officers who resign or are dismissed shall as a general rule be replaced within 3 months.
1.2.3 Meetings and related procedures

Meetings

The EB will hold regular meetings either by teleconference or face-to-face according to a schedule that is generally determined in the 4th quarter of the preceding year, with dates fixed according to quorum achieved and majority availability of the members. For teleconferences, care is taken to identify “reasonable” time periods, given the considerable time zone differences of participants.

Face-to-face meetings are held primarily during (breast) cancer conferences that most members attend. The EB also holds at least one annual 1.5 day strategic “retreat”, generally outside of a planned conference.

BIG HQ organizes all teleconferences and meetings of the EB and attends EB meetings. BIG HQ (through the CEO) has one vote on issues requiring a vote (unless there is a conflict of interest). The EB may at its discretion decide to hold some executive sessions without BIG HQ present.

BIG EB members are also expected to attend the BIG Scientific and General Assembly meetings, and will be expected to co-chair parts of those meetings. BIG EB members are also always invited to the annual BIG-NABCG meetings.

Quorum and voting

Decisions of the EB are valid when 2/3 of the EB is present or represented by another EB member, who may hold no more than one power of attorney.

In general, decisions are taken by consensus, but formal votes may also be taken. In the case of a vote, a decision is deemed to be taken when there is a 2/3 majority of the votes, including that of BIG HQ. 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.

The EB Chair shall have a casting vote in the event of tied votes.

Reimbursement for travel and expenses

When meetings take place during conferences that EB members plan to attend in any case, no reimbursement will be provided, unless the meeting will require extending the stay and therefore incurring extra costs. BIG can also cover the costs of EB members attending only the specific meeting at hand (e.g., BIG Scientific Meeting) and not the conference with which it is associated. When BIG members are invited to participate in meetings outside regular conferences, such as ad hoc face-to-face meetings for a working group or task force, as well as the annual retreat, 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 (Policy BIG-04).

Agenda and Minutes

A meeting agenda is drafted by the BIG HQ CEO, in consultation with the Chair, and is circulated together with any background documents to EB members, 2 – 3 days prior to a scheduled TC and approximately 1 week before a F2F meeting.
Minutes are prepared by BIG HQ staff members attending the EB meeting, as designated in advance. Within 7 working days of the meeting, draft minutes are circulated to EB members, who are expected to provide comments/amendments within 10 working days. Final minutes are signed by the Chair and the Vice-Chair or Treasurer (or in the absence of two of three officers, by another EB member present), sent to the EB members, and filed at BIG HQ.

1.2.4 Expectations

EB members must meet the requirements described in section 1.3, and above all are expected to serve in the best interests of BIG as a whole, rather than to use the position to promote the particular interests of the member group or other organizations with which s/he may be affiliated. This includes setting and developing the short-and-long-term strategy of BIG, analysing and determining acceptable levels of risk, working in a manner to enhance and protect BIG’s good reputation and to secure BIG’s long-term viability, and holding regular governance reviews and discussing succession planning.

In practical terms, each member on the EB is expected to commit considerable time and effort to the Association. This includes but is not restricted to:

- participation in most teleconferences/meetings, including the retreat
- preparing in advance for EB meetings (reading background materials, responding to emails, etc);
- responsiveness to BIG HQ for questions and advice
- being involved in BIG fundraising (to the extent possible without conflicting with local obligations) and other initiatives that support the BIG network.

EB members are expected to apply the following additional principles in their engagement as trustees of BIG:

- Work within BIG’s statutes and laws governing BIG as an association; this includes respecting principles of Good Clinical Practice in all of BIG’s research undertakings, and abiding by guidelines, policies or procedures established to safeguard these principles
- Not use BIG for financial or material gain, to identify potential conflicts of interest and manage them transparently and effectively
- BIG EB members are required to update their conflict of interest/financial disclosure forms on an annual basis, according to BIG’s policy (BIG-03). BIG EB members are also expected to report any new potential conflicts of interest whenever they arise, including during EB teleconferences and meetings in which topics are discussed that could give rise to such conflict. The other EB members present will decide on the degree to which the potential/actual conflict has bearing and, if needed, the conflicted member will be asked to step out of a discussion.
- Maintain confidentiality and respect intellectual property
  - As a general principle, all topics discussed at BIG EB, BIG Scientific and General Assembly meetings are confidential and indicated as such, as are meeting minutes and many other communications/documents circulated by BIG HQ. Moreover, study concepts generated by a member group and shared with the BIG EB prior to being presented at BIG meetings are considered to be that group’s intellectual property, unless clearly expressed otherwise. What is meant by this is that a BIG EB member may not unfairly use his/her position to “acquire” and implement the ideas of others.
  - Keep updated about the breast cancer research field and broader environment in which BIG works
  - Commit to attending all or most meetings of the EB, as well as BIG scientific and general assembly meetings, providing apologies when this is not possible
  - Prepare and participate actively in meetings, and being responsive to BIG HQ queries
• Engage in respectful, courteous and objective discussion, even when disagreements may arise, whether with other EB members, BIG members in general, or BIG HQ staff
• Regularly review their own performance (as a collective and as individuals) as well as that of the CEO (see Section 1.2.5)
• Respect and promote majority decisions, even when they may differ from individual personal opinions, supporting the work of the group and not acting unilaterally to the contrary
• When speaking on behalf of BIG, be clear about distinguishing a BIG position from a personal opinion, whenever relevant
• Respect BIG’s Mission and Principles of Research Conduct (Policy BIG-01), BIG’s Code of Conduct (Policy BIG-19) and all other BIG policies aimed at ensuring the good and reputable conduct of BIG.

1.2.5 Review of board and individual performance

The BIG Chair will initiate reviews of the overall EB performance as well as a review of individual performance, for example through self-assessment surveys and discussion and / or individual interviews. The BIG Chair is also responsible for initiating reviews of the BIG CEO’s performance. Reviews will take place on a two-yearly basis.

Included in assessing EB performance is individual presence and contribution to the board. It should be noted that absences from more than 20% of all EB meetings in any one-year period, in combination with no or few reactions/replies to messages from the HQ for the same period, constitute grounds for review of performance of an individual EB member. The result of the review may potentially lead to removal/replacement of the EB member.

The following steps should be followed to assure that the individual has been given every opportunity to re-establish his/her commitment or resign:
• HQ informs the Chair of the EB if a member is subject to reconsideration of EB membership, according to the above;
• the EB Chair contacts the individual to identify reasons for lack of attendance/reaction to communications from BIG HQ;
• following EB Chair’s consultation, the EB – excluding the member concerned – has the authority to formulate recommendations, including to remove that member from the EB (the latter requiring endorsement by the GA if that member has been directly elected by the GA);
• the EB Chair informs the individual about the outcome of this process.

In case the Chair of the EB is the subject of concern, the Vice-Chair will be consulted (or the Treasurer in the absence of a Vice-Chair) and then proceed as above.

1.2.6 Induction of Board Members

BIG aims to provide EB Members with the induction and support to carry out their role effectively.

EB Members will be provided with a copy of the Governance Manual and referred to the organisation’s website, which contains a wealth of material about BIG’s work.

Formal induction sessions are organised by the BIG HQ office and the BIG Chair to take EB members through the history, legal structure, vision, values, strategy and plans of the organisation and an overview of the management and governance functions.
1.2.7 Confidentiality and Conflict of Interest

The EB Member understands that all Confidential Information (meaning, without limitation, all written, oral or other scientific, medical, business, financial, technical or administrative information connected with a Study or other matter, methodology, procedures, proposed procedures, tests, equipment, data, patent applications, computer software -including, without limitation, any related codes, standard operating procedures, documentation, contracts, reports, know-how, premises, staff, investigators and collaborators, any and all other similar information, data, materials communicated to him/her as well as all internal discussions with the BIG EB or BIG HQ) are to be kept in strict confidence and used for the purposes of carrying out the EB Member function only.

In the event that the EB Member is requested or required by Applicable Laws, regulations or by final judicial decision to disclose any Confidential Information, he / she shall provide BIG with prompt notice of any such request or requirement. Should the EB Member be compelled by such legal process to disclose Confidential Information, he/she may disclose only that portion of the Confidential Information that is compelled to be disclosed.

Upon the first request of BIG, the EB Member undertakes to cease using the Confidential Information for any purpose and to promptly return all information and all materials (if any) communicated in any form, containing or reflecting any Confidential Information and to destroy any copies or other kinds of reproductions thereof, without retaining any copies or extracts in whole or in part thereof, except one for keeping track of its confidentiality obligations. Confidential Information regardless of form, the return of which BIG has not required, or which has not been thus remitted, must be destroyed.

The confidentiality provision of this Charter shall survive the expiration or termination of this Charter as well as in case of discontinuation of the EB Member’s activities for BIG, until such Confidential Information falls in the public domain, without fault of the EB Member.

The EB Member also understands that he/she shall have no direct / indirect conflict of interest in serving as EB Member for BIG. The EB Member agrees to notify BIG should such a conflict arise, and also agrees to complete a Conflict of Interest / financial declaration when required by BIG.
1.3 Executive Board Member position description

Required skills

- Expertise in one or more of following areas, in connection with breast cancer (for the scientific areas):
  - medical oncology
  - gynecological oncology
  - surgery
  - radiation therapy
  - radiology
  - biostatistics
  - molecular pathology
  - bioinformatics / related technologies
  - translational research
  - business / finance / investments

- Have demonstrated experience in the governance of one or more other organizations

- Public speaking experience (international conferences, etc)

Optional experience

- Grant-writing / fundraising
- Communications / PR / media
- Organizational management
- Patient advocacy

Essential qualities

- Have a strong code of ethics to ensure that clinical trials and research programs under the BIG umbrella are conducted to the highest quality standards and BIG principles of research conduct (Policy BIG-01)
- Be willing to take on additional responsibilities when needed, e.g., attend ad hoc meetings with pharmaceutical industry partners, represent BIG with other stakeholders, participate in task forces or working groups, support fundraising initiatives
- Be a transparent team player, committed to full disclosure about perceived and actual conflicts of interest
- Be responsive to requests from BIG HQ for questions / advice
- Serve as an ambassador for BIG as a whole
- Excellent spoken and written English

Time investment

Approximately 10 working day equivalents (~80 hours) per year. This estimate comprises the time required for attending regular teleconferences, face-to-face meetings, an annual retreat, and for reading of background materials, responding to emails, etc.

Most of the face-to-face meetings will be scheduled at (breast) cancer conferences.

Compensation

There is no monetary compensation for the function; however, BIG EB members enjoy substantial visibility in the international breast cancer arena. Expenses related to travel for BIG-related meetings will be reimbursed according to BIG’s travel and expenses policy (BIG-04).
1.4 BIG Chair charter

This charter applies to the individual selected by the BIG Executive Board (EB) to serve as Chair, both as Chair of the association and of the EB.

1.4.1 Responsibilities

The Chair’s specific responsibilities include:

- Working to realize BIG’s vision and mission by mobilizing member groups to move towards common research goals under the BIG umbrella, while respecting the diversity of perspectives represented.
- Leading the EB to keep the focus of the board on high quality governance decision-making, including the strategy behind clinical study and research programme development, organizational strategy and performance, assessment of risk, and succession planning.
- Working closely with BIG Headquarters (BIG HQ) to ensure that clinical trials and research programs under the BIG umbrella are conducted to the highest quality standards and BIG principles of research conduct so as to protect BIG’s reputation as an academic leader.
- Encouraging and leading open discussion about perceived and actual conflicts of interest, including the Chair’s own.
- Holding BIG EB members to account for behaviours not in accord with BIG’s Code of Conduct, the BIG EB Charter, and BIG’s Mission and Research Principles, or otherwise harmful to BIG and its reputation, and initiating steps to dismiss EB members in case the issues cannot be resolved.
- Engaging with BIG’s different stakeholders to further BIG’s mission and strategy: potential/actual pharmaceutical and biotech industry partners, group members, other cancer organizations, various funding bodies, fundraising events, regulatory agencies, government officials, patient advocates, insurers, or others.
- Playing an active role in the ongoing evaluation of BIG as an organization, its governance, headquarters, members and all related aspects. This includes:
  - Leading EB performance reviews, both as a group and individually.
  - Line-managing and evaluate the performance of BIG’s CEO, including initiating steps to dismiss the CEO in case there are issues that cannot be resolved.
  - Performance reviews will generally take place on a two-yearly basis and may include self-assessment and other surveys, discussion, individual interviews or other “good practice” of evaluating performance.
- Taking difficult decisions in a fair and objective manner based on an assessment of facts and ensuring that effective and transparent decision-making processes are in place.
- Casting the final vote in case the vote of the EB is tied.

1.4.2 Expectations

The BIG Chair plays a leading role in the association. She or he provides strong leadership for the organization and the EB, ensuring that the EB keeps focused on governing the association, keeping this distinct from the complementary management role of the BIG Headquarters.

In this respect, the Chair ensures that...
• High-level organizational strategies and policies are in place
• BIG operates in a fiscally responsible way
• Risk is evaluated and managed
• Clear, ethical, and accountable decisions consistent with BIG’s vision, mission, strategies and principles are taken
• Performance is regularly monitored at different levels of the organization
• BIG’s reputation is protected

It is therefore expected that the BIG Chair demonstrates a strong commitment to BIG in both word and action. The Chair must therefore ensure that decisions are taken for the good of the association, upholding its mission and principles, and not to benefit individual agendas. In so doing the Chair must be credible able to demonstrate objectivity and independent thought, leading the EB to take democratic decisions and defending the positions ultimately taken, regardless of personal opinion.

1.4.3 Measurement of performance
The Chair’s performance will be evaluated as part of the overall performance review process, for example in assessment (through surveys / in discussion) by other EB members and / or BIG membership as a whole.

1.4.4 Confidentiality and Conflict of Interest
The Chair understands that all Confidential Information (meaning, without limitation, all written, oral or other scientific, medical, business, financial, technical or administrative information connected with a Study or other matter, methodology, procedures, proposed procedures, tests, equipment, data, patent applications, computer software -including, without limitation, any related codes-, standard operating procedures, documentation, contracts, reports, know-how, premises, staff, investigators and collaborators, any and all other similar information, data, materials communicated to him/her as well as all internal discussions with the BIG EB or BIG HQ) are to be kept in strict confidence and used for the purposes of carrying out the BIG Chair function only.

In the event that the Chair is requested or required by Applicable Laws, regulations or by final judicial decision to disclose any Confidential Information, he / she shall provide BIG with prompt notice of any such request or requirement. Should the Chair be compelled by such legal process to disclose Confidential Information, he/she may disclose only that portion of the Confidential Information that is compelled to be disclosed.

Upon the first request of BIG, the Chair undertakes to cease using the Confidential Information for any purpose and to promptly return all information and all materials (if any) communicated in any form, containing or reflecting any Confidential Information and to destroy any copies or other kinds of reproductions thereof, without retaining any copies or extracts in whole or in part thereof, except one for keeping track of its confidentiality obligations. Confidential Information regardless of form, the return of which BIG has not required, or which has not been thus remitted, must be destroyed.

The confidentiality provision of this Charter shall survive the expiration or termination of this Charter as well as in case of discontinuation of the Chair’s activities for BIG, until such Confidential Information falls in the public domain, without fault of the Chair.
The Chair also understands that he/she shall have no direct / indirect conflict of interest in serving as Chair for BIG. The Chair agrees to notify BIG should such a conflict arise, and also agrees to complete a Conflict of Interest / financial declaration when required by BIG.

1.5 BIG Chair position description

1.5.1 Required skills and qualities

- Respected leader in the field of breast cancer, with vision and ability to bring perspectives from a broad range of member groups together to move towards common research goals under the one umbrella of BIG
- Have a strong code of ethics to ensure that clinical trials and research programs under the BIG umbrella are conducted to the highest quality standards and BIG principles of research conduct so as to protect BIG's reputation as an academic leader
- Previous experience of participating effectively in one or more boards, showing leadership qualities: these in particular include the potential to inspire engagement and commitment from each board member, to keep the focus of the board on organizational strategy and performance, and to hold open discussion about perceived and actual conflicts of interest
- Previous experience in working with executive staff in an organization and developing effective, collaborative relationships between the organizational leadership and staff responsible for managing the organization
- Able to engage easily with BIG's different stakeholders: potential / actual pharmaceutical and biotech industry partners, group members, other cancer organizations, various funding bodies, fundraising events, regulatory agencies, government officials, patient advocates, etc.
- Ability to take difficult decisions in a fair and objective manner and ensuring that effective and transparent decision-making processes are in place
- Commit to playing an active role in the ongoing evaluation of BIG as an organization, its governance, headquarters, members and all related aspects
- Should the new chair be selected from among current board members, that individual must have demonstrated his / her strong commitment to BIG on the basis of a strong % of participation in meetings and TCs as well as responsiveness to HQ queries, etc
- Be an excellent communicator in English, experienced in speaking in public in international events, regularly serving as a public ambassador for BIG.

1.5.2 Time investment

Approximately 20 working day equivalents (~160 hours) per year, comprising regular teleconferences, face-to-face meetings, an annual retreat, and including reading of background materials, responding to emails, etc.

Most of the face-to-face meetings will be scheduled at (breast) cancer conferences. Regular teleconferences (approximately weekly or bi-monthly), video-conferences or face-to-face meetings (approximately 1x month) are held with BIG HQ staff (with alternation between Chair coming to Brussels or senior staff travelling to Chair's location).
1.5.3 “Mentoring”
The new Chair will be mentored by the immediate Past-Chair for a period of 1 year. This will consist mainly of regular telephone calls and meetings, for example when the new Chair is in Brussels for meetings with BIG HQ staff.

1.5.4 Compensation
There is no monetary compensation for the function; however, the BIG EB chair enjoys substantial visibility in the international breast cancer arena. Expenses related to travel for BIG-related meetings will be reimbursed according to BIG’s travel and expenses policy (BIG-04).
1.6 General Assembly/Member Groups Charter

The General Assembly (GA) comprises all member groups and serves as the highest authority with respect to overall direction of the association. BIG has adopted this Charter, which applies to all BIG member groups.

1.6.1 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.

1.6.2 Role and responsibilities

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

- approve the main orientations and future strategies
- approve the budgets
- approve new member groups and the termination of membership
- nominate candidates to the Executive Board (EB) and fill half of any available EB seats by direct vote
- in case dismissal is proposed of an EB member who has been elected by the GA, to endorse (or not) that decision
- approve the dissolution of the Association.

1.6.3 Composition and structure

The GA is composed of all the member groups of the association. Each member group should assign one person to be its voting representative on the GA. Alternatively, to facilitate attendance at meetings and engagement in BIG activities, two individuals may be chosen as “co-voting” representatives, with the understanding that the group has only one vote.

Groups may be designated as either Effective or Adherent Members. Effective Members are Groups that meet the criteria of being legal entities and that conduct clinical trials and other research in breast cancer. Groups accepted to BIG as Adherent Members also designate a representative and have all the same rights as Effective Members, except to nominate members to the BIG Executive Board, and to vote. Reasons for accepting a group as an Adherent Member include 1) not being a legal entity and 2) not yet having had experience in breast cancer clinical trials.

The duration of the GA membership is linked to the approval and continuation of the membership of the group according to the criteria set out in section 1.6.5.

1.6.4 Meetings and related procedures

Meetings

GA meetings shall be held at least once per calendar year on a date proposed by the Executive Board, generally at a major oncology conference that a majority of BIG members attend (e.g.,
ASCO). Extraordinary GA meetings, in person, by teleconference or in the form of an electronic survey or vote, may be convened by the Executive Board whenever necessary and whenever the interests of BIG so require, either on the initiative of the Executive Board, or on request of at least half of the member groups. The BIG Headquarters (HQ) shall be represented at the GA meetings by one or more representatives without participating in the votes.

**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. Applicants accepted on a provisional basis (Adherent Members) 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 shall be passed by a simple majority of votes of the 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 Executive Board or by at least two-thirds of the member groups of the Association.

**Agenda and Minutes**

A meeting agenda is drafted by the BIG HQ CEO, in consultation with the BIG Executive Board, 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 10 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 are signed by the Chair and the Vice-Chair or Treasurer (or another board member if only one officer was present), filed at BIG HQ, and saved to the BIG members-only section of the website, together with presentations and background documents from the meeting.

In case the GA is requested to vote on a subject outside of a face-to-face or teleconference meeting, instead of an agenda, background information will be provided to enable BIG members to participate in the vote in an informed manner.

**1.6.5 Expectations**

**General terms**

BIG member groups, as represented by their (voting) representatives, should adhere and continue to 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.

The responsibilities of the person(s) assigned by a member group as its (co)-voting representative(s) on the GA include, or representative in the case of an Adherent Member, but are not restricted to, the following:

- serves as the main contact between the BIG Headquarters and the member group in general
- attends all the GA meetings or sends a substitute
• attends most of the scientific meetings
• ensures that the group participates in surveys initiated by BIG HQ (e.g., for interest in studies, about satisfaction within BIG, or issues requiring an electronic vote)
• keeps its members within the group informed about BIG activities.

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)-voting and non-voting representatives of BIG member groups. Groups are contacted about two months in advance of a meeting with a formal invitation and request for eventual proposals they wish to present and have discussed.

Presentation of trial ideas at BIG meetings
Each member group (Effective or Adherent) may present trial concepts to BIG scientific or GA meetings for consideration/development into a BIG trial, after approval by the Executive Board. Once a trial concept has been presented, and if from the discussion at a BIG scientific meeting it appears that there may be interest from other group members, BIG HQ will conduct a survey of BIG member groups to confirm interest. If a trial 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. The BIG group bringing the study to the network 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. It is important to note that it is not appropriate for a 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 (theodora.goulioti@bigagainstbc.org).

Participation in Task Forces or Working Groups
From time to time, the Executive Board may decide to issue calls for BIG member groups to nominate individuals with specific expertise to participate in a task force or working group dedicated to exploring a particular topic. All 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).

Participation in BIG studies
The countries in which a study will take place is a sponsor (pharmaceutical or academic) decision, and thus interest surveys are distributed to 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 groups will not be able to participate in all the trials in which they are interested.
Moreover, because of the sponsor’s role in determining which countries are included or not in a study, BIG members are not evaluated for their participation in trials.

**Attendance at BIG meetings**
BIG members are expected to try to attend BIG scientific and GA meetings, including “virtual” (electronic voting) ones. For the latter (GA, face-to-face or virtual) a quorum of participation (50%) must be met and for any decisions that affect the statutes, at least 66% of BIG Effective Members must approve the proposed changes. 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 when it is not possible.

**BIG-NABCG Annual meetings**
BIG and the North American Breast Cancer Group (NABCG) have been holding annual brainstorming meetings since 2005. These events are supported by the Breast Cancer Research Foundation (BCRF) and organized by a BIG-NABCG “Coordinating Committee”, consisting of two members from the BIG EB, two members from NABCG leadership, 1 representative from the U.S. National Cancer Institute, 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, the BIG-NABCG Coordinating Committee limits participation in the meeting each year to a maximum of 60 participants in total, with half designated by BIG, and half from NABCG.

On the BIG side, the only “fixed” invitees are members of the BIG Executive Board, any BIG-designated co-chairs of active working groups, the few BIG HQ physicians who provide support for the collaboration (such as by coordinating the working groups), and then people who are selected as experts for the main topic for the year. Consequently, the invitation list changes from year to year, and being invited one year does not mean that a person will automatically be invited the next year.

**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 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 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).

**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 (e.g., newsletters) and marked as confidential. Moreover, study concepts presented at BIG meetings by a group are considered to be 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. BIG groups are also invited to sign a master confidentiality agreement with BIG. Signing this document facilitates the exchange of study synopses, for example, and avoids the need to sign a new confidentiality agreement each time.

**Evaluation of membership**
BIG HQ tracks the presence of BIG member groups in meetings, and also whether groups are responsive to requests and surveys issued by BIG HQ. Absences from GA meetings and from
scientific meetings in combination with no reactions/replies to messages from the HQ 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 group:

- BIG HQ informs the EB if a member group is subject to reconsideration of membership, according to the above;
- the EB Chair contacts the member group voting representative in an effort to identify reasons for lack of attendance/reaction to communications from BIG HQ;
- following the EB Chair’s consultation, the EB has the authority to formulate recommendations that will be submitted to the GA for discussion / approval.

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.
1.7 Advisor Charter

1.7.1 Scope
This charter applies to ADD PERSON’s NAME (henceforth referred to as Advisor), appointed by the BIG’s Executive Board (EB) as Advisor to BIG in accordance with BIG’s statutes.

1.7.2 Role and Responsibilities
The Advisor has been selected for his/her specific expertise and/or role in the founding of BIG is primarily responsible for:

- providing advice to the BIG EB with regard to new drugs, new uses for old drugs, or other trends
- suggesting other ideas that would be in the best interest of BIG and might be considered by the EB, bearing in mind BIG’s mission, vision, values and respecting BIG’s principles of research conduct
- providing concrete recommendations, advice and guidance to the EB and contributing to presentations to BIG member groups on the preceding topics when requested
- attending BIG EB teleconferences / face-to-face meetings as an ex-officio (non-voting) member when requested by the EB and feasible
- attending BIG EB retreats or other special meetings when requested and feasible

1.7.3 Meetings and related procedures
Meetings and minutes
BIG HQ will organize any teleconferences and meetings required by the Advisor to fulfil his / her role and will be responsible for drafting the respective minutes. Within 7 working days of the meeting, draft minutes are circulated to the Advisor, who is expected to provide comments/ amendments within 7 working days. The final minutes will be made available to the BIG EB.

Reimbursement for travel and expenses
BIG will reimburse expenses incurred by the Advisor to attend face-to-face meetings requested by the EB, as long as they are in line with the principles and procedures outlined in BIG’s travel and expenses policy (POL BIG-04).

1.7.4 Expectations
The Advisor is expected to serve in the best interests of BIG as a whole, rather than to use the position to promote the particular interests of the member group or other organizations with which s/he may be affiliated.

In practical terms, the Advisor is expected to:

- participate in the teleconferences / meetings required to carry out his/ her function
- prepare in advance if required (reading background materials, responding to emails, etc);
be responsive to BIG HQ for questions or other queries sent in order to carry out the Advisor function for the BIG EB

The Advisor is also expected to apply the following additional principles in his / her engagement on behalf of BIG:

- Work within BIG’s statutes and laws governing BIG as an association; this includes respecting principles of Good Clinical Practice in all of BIG’s research undertakings, and abiding by guidelines, policies or procedures established to safeguard these principles
- Not use BIG for financial or material gain, to Identify potential conflicts of interest (by providing a conflict of interest / financial disclosure form on an annual basis, according to BIG’s policy (BIG-03) and manage them transparently and effectively. The EB will decide on the degree to which the potential / actual conflict has bearing on the Advisor’s ability to carry out his/ her function.
- Maintain confidentiality and respect intellectual property
  As a general principle, all topics discussed at Advisor, BIG EB, BIG Scientific or other meetings are confidential and indicated as such, as are meeting minutes and many other communications / documents circulated by BIG HQ. The Advisor may not unfairly use his/ her position to “acquire” and implement the ideas of others.
- Engage in respectful, courteous and objective discussion, even when disagreements may arise, whether with other EB members, BIG members in general, or BIG HQ staff
- When speaking on behalf of BIG, be clear about distinguishing a BIG position from a personal opinion, whenever relevant
- Understand that he/ she does not have any decision-making authority for BIG
- Respect BIG’s Mission and Principles of Research Conduct (Policy BIG-01), BIG’s Code of Conduct (Policy BIG-19) and all other BIG policies aimed at ensuring the good and reputable conduct of BIG.

As long as the Advisor is acting within his or her mandate as approved by the BIG EB, the Advisor will not be held legally liable for advice provided during his / her mandate. For clarity, the Advisor may not engage BIG in any legal agreements.

1.7.5 Confidentiality and Conflict of Interest
The Advisor understands that all Confidential Information (meaning, without limitation, all written, oral or other scientific, medical, business, financial, technical or administrative information connected with a Study or other matter, methodology, procedures, proposed procedures, tests, equipment, data, patent applications, computer software -including, without limitation, any related codes-, standard operating procedures, documentation, contracts, reports, know-how, premises, staff, investigators and collaborators, any and all other similar information, data, materials communicated to him/her as well as all internal discussions with the BIG EB or BIG HQ) are to be kept in strict confidence and used for the purposes of carrying out the Advisor function only.

In the event that the Advisor is requested or required by Applicable Laws, regulations or by final judicial decision to disclose any Confidential Information, he / she shall provide BIG with prompt notice of any such request or requirement. Should the Advisor be compelled by such
legal process to disclose Confidential Information, he/she may disclose only that portion of the Confidential Information that is compelled to be disclosed.

Upon the first request of BIG, the Advisor undertakes to cease using the Confidential Information for any purpose and to promptly return all information and all materials (if any) communicated in any form, containing or reflecting any Confidential Information and to destroy any copies or other kinds of reproductions thereof, without retaining any copies or extracts in whole or in part thereof, except one for keeping track of its confidentiality obligations. Confidential Information regardless of form, the return of which BIG has not required, or which has not been thus remitted, must be destroyed.

The confidentiality provision of this Charter shall survive the expiration or termination of this Charter as well as in case of discontinuation of the Advisor's activities for BIG, until such Confidential Information falls in the public domain, without fault of the Advisor.

The Advisor also understands that he/she shall have no direct / indirect conflict of interest in serving as Advisor for BIG. The Advisor agrees to notify BIG should such a conflict arise, and also agrees to complete a Conflict of Interest declaration if required by BIG.

1.7.6 Term
The Advisor may resign at any time in writing (to the BIG Chair and BIG HQ) and without a specific notice period. The EB may also determine that the contributions of the Advisor are no longer needed and will inform the Advisor of this in writing, specifying the effective date.
1.8 Immediate Past Chair Charter

1.8.1 Scope
This charter applies to the Immediate Past Chair (IPC). The tenure of the IPC is one year, beginning from the time that the new Chair is selected by the EB and starts his or her term.

1.8.2 Expectations
The IPC plays an important role in the transition of association leadership. She or he supports the new Chair – and the EB – with her / his knowledge and experience about the organization. S/he is available to advise the Chair on a variety of matters, to take up specific tasks as identified by the EB, and will participate in meetings and teleconferences of the EB. However, the IPC has no independent decision-making or signature authority. The IPC must also abide by any requirements set by BIG policies, guidelines, Code of Conduct or other documents related to the good functioning of BIG.

1.8.3 Responsibilities
The IPC’s specific responsibilities include
• Participating in regular teleconferences / meetings with the incoming Chair
• Participating in teleconferences and face-to-face meetings (including retreats) of the BIG EB, and having the right to a vote
• Attending BIG Scientific Meetings and the General Assembly
• Contributing actively to specific initiatives, such as scientific working groups, task forces, or fundraising events, as determined by the EB
• Suggesting scientific or other ideas that would be in the best interest of BIG and might be considered by the EB, bearing in mind BIG’s mission, vision, values and respecting BIG’s principles of research conduct
• Providing recommendations, advice and guidance to the Chair when requested

The IPC will apply the following additional principles in her / his engagement on behalf of BIG:
• Work within BIG’s statutes and laws governing BIG as an association; this includes respecting principles of Good Clinical Practice in all of BIG’s research undertakings, and abiding by guidelines, policies or procedures established to safeguard these principles
• Not use BIG for financial or material gain, and to report potential conflicts of interest (by providing a conflict of interest / financial disclosure form on an annual basis), according to BIG’s policy (BIG-03). The EB will decide on the degree to which the potential / actual conflict has bearing on the ICP’s ability to carry out her / his function.
• Maintain confidentiality and respect intellectual property

As a general principle, all topics discussed at meetings attended by the IPC are confidential and indicated as such, as are meeting minutes and many other communications / documents circulated by BIG HQ. The IPC may not unfairly use his/ her position to “acquire” and implement the ideas of others.
• Engage in respectful, courteous and objective discussion, even when disagreements may arise, whether with other EB members, BIG members in general, or BIG Headquarters (HQ) staff
• When speaking on behalf of BIG, be clear about distinguishing a BIG position from a personal opinion, whenever relevant
• Understand that she / he does not have any decision-making authority for BIG.
1.8.4 Compensation
There is no monetary compensation for the function of IPC; however, she or he still enjoys substantial visibility in the international breast cancer arena. Expenses related to travel for BIG-related meetings will be reimbursed according to BIG’s travel and expenses policy (BIG-04).

1.8.5 Confidentiality and Conflict of Interest
The IPC understands that all Confidential Information (meaning, without limitation, all written, oral or other scientific, medical, business, financial, technical or administrative information connected with a Study or other matter, methodology, procedures, proposed procedures, tests, equipment, data, patent applications, computer software – including, without limitation, any related codes –, standard operating procedures, documentation, contracts, reports, know-how, premises, staff, investigators and collaborators, any and all other similar information, data, materials communicated to her/him as well as all internal discussions with the BIG EB or BIG HQ) are to be kept in strict confidence and used for the purposes of carrying out the BIG IPC function only.

In the event that the IPC is requested or required by Applicable Laws, regulations or by final judicial decision to disclose any Confidential Information, s/he shall provide BIG with prompt notice of any such request or requirement. Should the IPC be compelled by such legal process to disclose Confidential Information, s/he may disclose only that portion of the Confidential Information that is compelled to be disclosed.

Upon the first request of BIG, the IPC undertakes to cease using the Confidential Information for any purpose and to promptly return all information and all materials (if any) communicated in any form, containing or reflecting any Confidential Information and to destroy any copies or other kinds of reproductions thereof, without retaining any copies or extracts in whole or in part thereof, except one for keeping track of its confidentiality obligations. Confidential Information regardless of form, the return of which BIG has not required, or which has not been thus remitted, must be destroyed.

The confidentiality provision of this Charter shall survive the expiration or termination of this Charter as well as in case of discontinuation of the IPC’s activities for BIG, until such Confidential Information falls in the public domain, without fault of the IPC.

The IPC also understands that he/she shall have no direct / indirect conflict of interest in serving as IPC for BIG. The IPC agrees to notify the BIG Chair and BIG HQ should such a conflict arise, and also agrees to complete a Conflict of Interest declaration if required.

1.8.6 Liability
As long as the IPC is acting within his or her mandate as approved by the BIG EB, the s/he will not be held legally liable for advice provided during this period. For clarity, the IPC may not engage BIG in any legal agreements.
1.9 Immediate Past Chair position description

1.9.1 Role
- In general, advises the new Chair and the EB regarding past experience and practices and other matters to assist the EB in governing BIG.
- As needed, provides specific support to the Chair and other EB members on a range of topics.
- Engages actively in specific task forces, working groups or other activities as mutually agreed between the Chair / EB and the Immediate Past Chair. Specific tasks will be discussed and agreed in an EB meeting and minuted accordingly.

1.9.2 Position description / requirements
- Have completed her / his mandate as Chair of the Breast International Group
- Respected leader in the field of breast cancer, supporting the new Chair and EB to achieve common research goals under the one umbrella of BIG
- Have a strong code of ethics to ensure that clinical trials and research programs and other activities under the BIG umbrella are conducted to the highest quality standards, BIG principles of research conduct and BIG’s Code of Conduct in order to protect BIG's reputation as an academic leader
- Be an excellent communicator in English, experienced in speaking in public in international events, serving as a public ambassador for BIG when requested.

1.9.3 Time investment
Approximately 10 working day equivalents (~80 hours), comprising regular teleconferences, face-to-face meetings, an annual retreat, and including reading of background materials, responding to emails, etc.
Most of the face-to-face meetings will be scheduled at (breast) cancer conferences; a few face-to-face meetings not associated with conferences may be held in Brussels or other locations to be determined by the EB.

1.9.4 Compensation
There is no monetary compensation for the function. Expenses related to travel for BIG-related meetings will be reimbursed according to BIG’s travel and expenses policy (BIG-04).
2. Policies

2.1 Code of conduct (Policy BIG-19)

2.1.1 Introduction
BIG is an international non-profit organisation for academic breast cancer research groups from around the world. BIG’s mission is to facilitate and accelerate breast cancer research at the international level by stimulating cooperation between its member groups and other academic networks, and collaborating with, but working independently from, the pharmaceutical industry.
BIG is committed to its vision of finding a cure for breast cancer through global collaboration and research, its mission to facilitate breast cancer research internationally, and to conduct its research following specific academic principles (Policy BIG-01, “BIG Mission & Principles of Research Conduct”).
In line with BIG’s vision and mission, which aim ultimately to better and extend the lives of patients confronted with breast cancer, BIG strives to reflect the following values in all that it does: accountability, integrity, selflessness, objectivity, transparency, honesty, leadership, trust, solidarity, respect, fairness, and excellence.
The purpose of this policy is to provide guidance about BIG’s expectations concerning appropriate professional and ethical behavior in the context of conducting business under the umbrella of BIG, as well as to enforce its compliance.

2.1.2 Scope
This policy applies to BIG Executive Board (EB) members, BIG Headquarters (HQ) Staff, Voting Representatives of BIG Member Groups, BIG Study Principal Investigators, BIG designated Advisors, or any others designated as a (co)-Chair or member of a BIG working group, task force or committee, or other activity (“BIG Business”) in which s/he directly or indirectly represents BIG (collectively referred to as “BIG Members” for the purposes of this guideline).

2.1.3 Mission
In conducting BIG Business, BIG Members, including the BIG EB and BIG HQ, will
- continuously strive to uphold BIG’s mission, principles of research conduct, and values.
- work and behave in a spirit to support and defend academic research principles in order to protect BIG’s reputation and to avoid contributing to the impression that BIG or any of its members are “disguised” contract research organisations (CROs)
- be committed to excellence in breast cancer research with the objective of working in the best interests of patients

2.1.4 Legal Compliance and Governance
In conducting BIG Business, BIG Members, including the BIG EB and BIG HQ, will
- Work within the law
- Work within BIG’s articles of incorporation (“statutes”) and related governance documents (e.g., function-specific charters)
- Respect the confidentiality as required in the agreements, charters, policies or statements as provided in the context of information made available on such a basis
- Respect the confidentiality of information presented or provided during BIG Scientific, General Assembly or other meetings, or as otherwise disseminated confidentially through various communications channels to BIG members
• Comply with BIG’s Anti-Bribery & Anti-Corruption Policy (LEG-07)

In conducting BIG Business, BIG HQ, will
• Respect privacy and handle personal data in compliance with privacy laws and BIG’s Data Privacy Policy (LEG-06)

2.1.5 Professional Integrity and Accountability
In conducting BIG Business, BIG Members, including the BIG EB and BIG HQ, will
• Work in the best interests of BIG as an organization, rather than pursuing personal agendas
• Agree that when presenting a study concept in a BIG Scientific Meeting, and if one or more other BIG groups indicate potential interest during such meeting, that the study be will run under the BIG umbrella according to one of the BIG trial models, and not taken outside of the BIG network
• If serving on a committee, working group, task force, as a BIG Study principal investigator or otherwise engaged in BIG Business, commit to
  ➢ Working in good faith to accomplish the objectives and responsibly carry out the role attributed
  ➢ Preparing for and attending (or apologizing for) meetings and engaging constructively and sensitively in related discussions and decision-making, participating in a vote whenever required
  ➢ Accepting the decisions taken according to the majority (or super-majority, as the case may be) decision and not take individual and contrary action
  ➢ Gaining a sound and up-to-date knowledge of BIG and the activity engaged in by reading information provided for that purpose or participating in any induction and training provided
• Be responsible and accountable for own actions and decisions taken
• Protect BIG’s assets and reputation
  ➢ Use computers, phones or other property for legitimate business purposes and not for private activities or personal gain
  ➢ Agree to proper use of email, internet and social media, meaning that it must not be used for illegal, offensive, disruptive or discriminating content
  ➢ Protect BIG’s intellectual property and use it only according to legally agreed upon terms
  ➢ If expressing a personal opinion rather than a position of BIG, clearly make this distinction
• Be open to scrutiny and sanction

In conducting BIG Business, the BIG EB and BIG HQ will
• be accountable to BIG members, collectively represented in the General Assembly.

2.1.6 Responsible Stewardship
In conducting BIG Business, BIG Members, including the BIG EB and BIG HQ, will
• Ensure that spending practices and policies are fair, reasonable and appropriate to fill the mission of BIG; this includes being frugal and working within approved budgets and guidelines in order to protect the financial health of BIG
• Raise and use funds in a manner that are ethical, compliant with donor intent, and coherent with BIG’s role as a healthcare and non-profit organization
• Comply with BIG’s Travel and Expenses Policy (BIG-04) or comparable study-specific expenses policies whenever required
• Follow compensation policies that are in line with industry practice and appropriate for BIG as a non-profit organization
• Have effective accounting systems in place, with appropriate controls and factually accurate and complete reporting

2.1.7 Disclosure and Transparency
In conducting BIG Business, BIG Members will
• Comply with BIG’s Conflict of Interest and Financial Disclosure policy (BIG-03) whenever required
• Not allow personal interests to conflict with the duty to act in the interest of BIG; if there is the potential for perceived or actual conflict of interest, declare this so that it can be managed according to the governing policy
• Retain all data and records according to legal requirements and industry standards

In conducting BIG Business, BIG EB and BIG HQ will
• Ensure that communication with BIG Groups is open and transparent in order to create and maintain an environment of trust

2.1.8 Relationships
In conducting BIG Business, BIG Members, including the BIG EB and BIG HQ, will
• Establish relationships on the principles of mutual respect, fairness, support, professionalism and trust.
• Not tolerate any form of discrimination, harassment, intimidation, humiliation, denigration, abuse (verbal, physical, sexual or other) or other action intended to intimidate or manipulate may be tolerated.

In conducting BIG Business, the BIG EB and BIG HQ commit to
• working as a team in a relationship of mutual respect, and acknowledging the distinction and complementarity in their roles
• interacting with BIG Members in a spirit of fairness and respect, ensuring that participation in BIG activities is based on merit and other, transparently communicated, objective criteria
• providing equal opportunities within the organization, regardless of race, ethnicity, religion, disability, age, sexual orientation or geography.

2.1.9 Corporate Social Responsibility
In conducting BIG Business, BIG HQ will
• Make best efforts to make efficient and responsible use of resources, and commits to recycling and reducing waste whenever possible
• Strive to be an excellent employer, providing its staff members and any other individuals involved in BIG business with a safe, healthy and otherwise positive working environment that includes regular training and opportunities professional development
• Be cognizant of work-stress related hazards such as “burn-out” and commits to vigilance of this and to support an appropriate work-life balance

2.1.10 Staff
In conducting BIG Business, BIG Members, including the BIG EB and BIG HQ, will
• be expected to understand, accept and respect the difference in roles between the 
  Board, and the Management of BIG HQ, ensuring that the Board and the BIG HQ team 
  work effectively and cohesively for the benefit of the organisation, and develop a mutually 
  supportive and loyal relationship.

In conducting BIG Business, the BIG EB will
• be careful, having given the CEO delegated authority, - individually and collectively - not 
  to undermine this delegation by word or action.

In conducting BIG Business, the BIG EB (in the case of the CEO) and BIG HQ (for all other 
  cases) will
• act fairly and in accordance with good employment and equal opportunities principles in 
  making decisions affecting the appointment, recruitment, professional development, 
  appraisal, remuneration and discipline of the CEO and other staff.

2.1.11 Scrutiny and Sanctions
• All individuals engaged in activities on behalf of BIG are subject to scrutiny with regard to 
  their performance and behaviour; this means compliance with requirements of any 
  agreements or charters governing the respective activity, or working contracts and 
  position descriptions
• Any concerns should be directed as follows:
  ➢ About a BIG EB Member: to the BIG Chair, unless it is the Chair, in which case the 
    Vice-Chair
  ➢ About a BIG HQ CEO: to the BIG Chair
  ➢ About any other BIG HQ staff member: to the CEO
  ➢ About a BIG Member Group, BIG Study Principal Investigators, BIG designated 
    Advisors, or any others designated as a member of a BIG working group, task force 
    or committee or other activity in which s/he directly or indirectly represents BIG: to 
    the CEO, who will escalate as needed to the BIG Chair / EB

• All issues will be reviewed in a fair and objective manner, in consideration of the facts 
  available and the views of each party involved, and with the objective to be resolved in an 
  amicable manner
• In case an issue cannot be resolved in a productive manner, a third-party mediator may 
  be consulted
• If it is deemed that a serious breach has been committed, or that the issue at hand 
  cannot be resolved and/or presents a serious threat to BIG’s reputation, the individual or 
  Group concerned will be required to step down from his /her position / leave BIG.
2.2  Conflict of interest and financial disclosure (Policy BIG-03)

2.2.1  Introduction

Ethical behaviour involves demonstrating respect for key moral principles that include honesty, fairness, equality, dignity, diversity and individual rights. BIG as an international scientific research organization must adhere to the highest level of these principles in order to maintain its credibility as an organization as well as the credibility of the results issuing from any of the research activities conducted under BIG’s umbrella.

In particular, it is essential that any research programs and studies involving patients preserve their rights, safety and well-being. Acts or decisions taken within the scope of any research program, study or collaboration involving or having impact on patients shall set patients' best interests above all others, by following principles established to eliminate bias from the research process. This means that the individuals involved in developing, managing, or leading BIG Activity[ies] should have no interests that affect their impartiality and consequently patients' best interests.

The purpose of this policy is to clarify and explain BIG’s position on conflict of interest. It shall identify the areas where potential conflict of interest may be present and when disclosure of potential, actual, or perceived conflict of interest is needed. It also describes the process for such disclosure, including any limitations to activities that may consequently be imposed.

2.2.2  Scope

This policy applies to individuals who play a key role in developing, managing or leading BIG Activities, in particular those in decision-making and leadership positions for BIG Activities or in BIG as an organization such as but not limited to the members of the BIG Executive Board and BIG Headquarters directors.

2.2.3  Definitions

**BIG Activity (-ies)** means BIG research programs, studies, and collaborations, and any activities that support these areas.

**Company** is a for- or non-profit entity that develops, produces, markets, or distributes drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions. This definition mainly intends to include entities of the healthcare sector, or entities through which physicians provide clinical services directly to patients. However, BIG may choose to adopt a broader definition of “Company” if doing so would better address its interactions.

**Confidential Information** means all information not in the public domain (or information which entered the public domain pursuant to disclosure in violation) disclosed or provided or made available directly or indirectly by one Party to another, or which a Party obtained, in connection with the conduct of a BIG Activity.

**Charitable Contribution** means a gift, including an in-kind gift, given by a Company for use in furthering the organization’s charitable research purposes and in accordance with applicable tax rules and legal standards.

**Immediate Family Member(s)** means any one of the following legally competent persons: spouse, companion and children (including adopted children) or any other person with whom a covered individual shares income or assets and believes disclosure is relevant.
2.2.4 Principles

Independence
Individuals to whom this policy is addressed shall commit that their involvement in BIG Activities shall be independent of influence and may not have direct or indirect financial, professional or other relationships with Companies that may constitute potential, perceived or actual conflict of interest, as described in section 4.2.

Transparency
The conflict of interest policy and forms are available to BIG members and to the public. The individuals to whom this policy is addressed shall disclose all interests causing potential, actual or perceived conflict of interests as described in section 4.2, keeping in mind that patients' best interests should reign above any other interests and that individuals participating in BIG Activities should have no interests that could affect their impartiality in a given activity.

The conflict of interest forms filled in by the individuals in accordance with the Policy can be publicly disclosed by BIG through various media as identified as relevant by BIG, including, on but not limited to, BIG’s website.

Management of charitable contributions and research grants
• BIG shall control and review charitable contributions and research grants in a manner that is aligned with its strategic plan and mission and in conformity with the applicable legislation.
• BIG shall not permit Companies to select (or influence the selection of) recipients of charitable contributions and research grants.
• BIG shall not permit Companies that provide charitable contributions and research grants to receive intellectual property rights or royalties arising out of benefit research.
• BIG shall not permit Companies that provide charitable contributions and research grants to control or influence manuscripts that arise from the benefit research.
• BIG shall act independently in the selection of research topics and the conduct of the research itself. Upon request, BIG shall disclose any Company benefit received.

Clinical research and practice
BIG shall base its clinical research and practice on scientific evidence and shall follow a transparent policy development process that does not conflict with BIG principles and policies.

Conflict of interest

Financial Interest
The individual or his/her immediate family member has a financial interest in a BIG Activity as a whole or in part by:
• having pecuniary interest including membership in external committees, research councils, government bodies, professional departments acting within the field of oncology;
• participating in the board of a Company/ or shareholder of a Company having (commercial) relationship or partnership with BIG;
• having interests in companies who are suppliers or customers of BIG;
• receiving financial compensation for exerting influence to favour the implementation of the BIG Activity;
• having an interest on the outcome of the BIG Activity because of the way the payment is being arranged (e.g. royalties) or because the compensation could be higher for a favourable outcome;
• expecting funds for the performance of a research project (research grant);
• having any ownership interest, stock options, or other financial interest in any Company involved in the BIG Activity whose value cannot be readily determined through reference to public prices (generally, interests in a non-publicly traded corporation), or any equity interest in a publicly traded corporation that exceeds amount referred in the US Code of Federal Regulations, title 21, chapter I, part 54, § 54.2.

For avoidance of doubt, the following situations are also considered to be a financial conflict of interest:

• while serving as a principal investigator or chair / co-chair of a committee of a BIG study in which a pharmaceutical industry partner serves as sponsor, to receive honoraria or other direct personal payment from the sponsor for consulting, advisory board or similar activities; this is considered to be a conflict until the study primary endpoints are publicly presented / published (unless the study ends sooner for any reason).
• to earn a performance-based salary (e.g., receiving bonuses or other incentives) from a BIG group that coordinates / (co)-leads a BIG study (NB. receiving a fixed salary does not constitute a conflict of interest)

Professional interest
The individual or his/her immediate family member has a professional interest in the BIG Activity as a whole or in part by:
• contributing to specific tasks to bias decisions or influence others to change their decisions, in order to favour attainment of his/her own professional or personal goals;
• having proprietary interest in the tested product such as any intellectual property rights related to a patent, trademark, copyright or license involved in the BIG Activity;
• having the promise or expectation of specific publication or publicity related to a BIG Activity, other than that which is governed by BIG publication principles, study specific publication policies and plans, or approved by the BIG Executive Board, e.g., related to the marketing of a Product / Technology;
• Negotiations or arrangements regarding potential employment or affiliation.

Other interests
Potential, actual or perceived conflict of interest may arise:
• when an individual uses his / her position to gain any reward or advantage beyond what is considered to be standard for the specific BIG Activity, e.g., authorship, consulting activities, speaking engagements, expert testimony or other recognition of contributions according to BIG guidelines and policies;
• when a situation may potentially create bias or harm, or may be perceived to create bias or harm, whether intentionally or unintentionally;
• when the individual or his/her immediate family member has other interests in the BIG Activity as a whole or in part by:
  ➢ disclosing any Confidential Information obtained from the participation in a BIG Activity for personal gain, or sharing it with any other party, who does not have a specific need to know, so as to possibly benefit her/ him;
  ➢ having a sort of interest not here listed though his/her impartiality in conducting a BIG Activity could be questioned. In these circumstances, the individual shall disclose the fact and its relationship.
Some scenarios not represented here may also constitute potential, perceived or actual conflict of interest that could influence the impartiality of individuals engaged in BIG Activities and shall be handled on a case-by-case basis.
2.2.5 Procedure for Disclosure

The individuals assuming different roles in developing, managing, or leading BIG Activity (-ies) shall disclose interests that are potential or actual conflicts of interest, or that may be perceived as such according to the principles outlined above.

BIG Headquarters shall coordinate the collection of forms and the overall conflict of interest process; the BIG Executive Board serves as reviewer and decision-maker:

- BIG Headquarters shall provide the individuals addressed by this policy with a copy of this policy and BIG's Conflict of Interest and Financial Disclosure Form (Form BIG-03.2) for completion.  
- Forms shall be updated every year.  
- Whenever significant changes occur within the year period, said individuals have the responsibility to inform BIG Headquarters and update their form.  
- At least once per year, all new or updated forms shall be reviewed by the BIG Executive Board for any declared potential or actual conflict of interest. The BIG Executive Board shall review each such case and decide which actions are the most appropriate to be taken.  
- If the BIG Executive Board has identified an actual conflict of interest, the BIG Executive Board shall determine on a case by case basis the most appropriate action.  
- The individual who has the actual conflict of interest shall not be present in the deliberations of the BIG Executive Board. For avoidance of doubt, if the individual with a conflict of interest is an Executive Board member, he/she shall not be present for such deliberations and vote.  

BIG Headquarters reserves the right to make public any conflict of interest form filled in in accordance with the present Policy by publishing it on its website or any other media BIG deems appropriate for transparency purposes.

2.2.6 Failure to observe this policy

Failure to disclose a conflict of interest according to this policy could result in the loss of privileges to participate in BIG Activities. Possible breaches of this policy shall be brought to the attention of the BIG CEO, who shall bring the matter to the BIG Executive Board. In case the possible breach concerns the CEO, the matter shall be brought directly to the attention of the BIG Executive Board by anyone who becomes aware of such possible breach. In all cases, the BIG Executive Board shall investigate the issue and recommend whatever action it deems appropriate.
2.3 BIG Study Models (Policy BIG-08)

2.3.1 Introduction
BIG studies vary according to several factors: the level of involvement of BIG member groups (and their sites), other academic partners, and pharmaceutical / biotechnology industry partners; the role of BIG HQ; and the way in which a trial is introduced to and initiated in the BIG network.

This policy describes the requirements for studies to be conducted as a BIG study, the involvement of industry partners, the different types of BIG studies and the participation in BIG studies.

2.3.2 Requirements for BIG studies
All BIG studies:
- Must adhere to the BIG’s Mission and Principles of Research Conduct (Policy BIG-01);
- Involve two or more BIG member groups and their affiliated sites;
- Are presented to the BIG scientific community to allow input on the study design and/or to seek participation from other BIG groups;
- Must be approved by the BIG Executive Board;
- Will receive a BIG study number and use the BIG logo, to be used in addition to any other study numbers and/or logos;
- Will be supported by BIG HQ’s communication structure (e.g., newsletter, website, e-update);
- Require a contract with the sponsor of the study to cover the responsibilities, including liability and indemnification of BIG as a legal entity;
- Make a financial contribution to BIG HQ in the form of a BIG network fee (see Policy BIG-07, accessible on the BIG website in the Members area);
- Must have an academic study governance model with the academic partners holding the majority of votes in the governance bodies.

2.3.3 Role of pharmaceutical / biotechnology industry partners
The role of pharmaceutical / biotechnology industry partners ranges from highly involved to not involved at all. Typical examples are:
- Studies with an industry partner as the legal sponsor for the study, responsible for full funding of the study and for most of the operational aspects of the study;
- Studies with an academic partner as the legal sponsor and the industry partner providing only the study drug and/or financial support (e.g. grants);
- Academic studies with an industry partner providing only a technology service;
- Purely academic studies with no industry partner involved at all (for example, studies not involving study medications).
2.3.4 BIG study models
BIG studies typically correspond to four main models.

BIG Lead studies
BIG Lead studies are introduced to the BIG network by a representative from BIG leadership (e.g., Executive Board) or by an industry partner wishing to collaborate with BIG to develop the study. In BIG Lead studies, BIG collaborates with academic partners such as the BrEAST Data Centre and Frontier Science and Technology Research Foundation (FSTRF).

Sponsor: The legal sponsor is a pharmaceutical / biotechnology industry partner.

Responsibilities: BIG Headquarters is involved throughout the study and leads activities such as contracts, budgets, general communications, study governance and general scientific matters. BIG HQ also liaises with the BIG Executive Board to resolve any issues of strategy / principle. BIG collaborates with the BrEAST data centre and/or other academic partners such as Frontier Science & Technology Research Foundation (FSTRF), these entities usually leading activities such as protocol development, medical review, study data management and providing statistical leadership and support, eventually with other BIG member groups providing such expertise;

Input from BIG scientific community: The study is presented at an early stage of development to the BIG scientific community (e.g., during BIG Scientific Meetings) to allow input on the study design and, if needed, issues of strategic concern to BIG.

Contracts: BIG HQ (on behalf of the BIG Network) contracts with the sponsor for any preliminary agreements (e.g., Letter of Intent, Pre-study Agreement); BIG (on behalf of the BIG Network) and the other leading academic partners are parties to the main study agreement with the sponsor, which covers all study-specific responsibilities of BIG Headquarters, the academic study partners and BIG member groups.

Budget: All costs for the study activities of BIG Headquarters, the academic study partners and BIG member groups – as specified in the study budget – must be adequately covered by the industry sponsor.

BIG Co-Lead studies
BIG Co-Lead studies are introduced to the BIG network by a representative from BIG leadership (e.g., Executive Board), a BIG member group, or an industry partner seeking collaboration with the BIG network

Sponsor: BIG Co-Lead studies are sponsored by a pharmaceutical / biotechnology industry partner or by one of the co-lead groups.

Responsibilities: BIG Headquarters is involved in the early negotiations of the study and leads activities such as contracts, budgets, general communications and study governance. BIG HQ also liaises with the BIG Executive Board to resolve any issues of strategy / principle. The BIG co-lead group(s) lead(s) activities such as science, data management and statistics.

Input from BIG scientific community: The study is presented at an early stage of development to the BIG scientific community (e.g., during BIG Scientific Meetings) to allow input on the study design and, if needed, issues of strategic concern to BIG.

Contracts: BIG HQ (on behalf of the BIG Network) contracts with the industry partner (whether sponsor or not) for any preliminary agreements (e.g., Letter of Intent, Pre-study Agreement). BIG HQ (on behalf of the BIG Network) and the co-lead group(s) are party to the main study agreement, which covers all study-specific activities of BIG Headquarters, the academic study partners, the industry partner and BIG member groups.
**Budget:** If the sponsor of the study is an industry partner, all costs for the study activities of BIG Headquarters, the co-lead group(s) and BIG member groups – as specified in the study budget – must be adequately covered by the industry partner. If the sponsor is one of the co-lead groups or another academic organisation, additional funding may be needed in addition to the support and funding by the industry partner.

More details about the roles and responsibilities in Co-Lead studies can be found in Policy BIG-10 "Roles and Responsibilities in Co-Lead studies" (accessible on the BIG website in the Members Area).

**BIG Supporter studies**
Supporter studies are studies under the BIG umbrella that are developed and coordinated by a BIG member group or groups, with a limited role for BIG HQ.

**Sponsor:** The BIG member group is usually also the sponsor of the study; in some cases it may be an industry partner.

**Responsibilities:** The study is led and run by a BIG member group or groups and requires limited input and support from BIG HQ.

**Input from BIG scientific community:** Supporter studies may or may not receive scientific input from the BIG scientific community in the early development stage of the trial. Often they are brought to BIG primarily to seek participation from other BIG groups to increase patient accrual and are introduced as nearly finalized protocols or as already launched trials. However, some trials may also be introduced in early concept stages, allowing for considerable scientific input from BIG members (e.g., at BIG scientific meetings) before they are further developed.

**Contracts:** Supporter studies require a simple partnership contract between the leading member group(s) and BIG HQ (on behalf of the BIG Network) (e.g., to cover limited BIG liability and terms of the network fee).

**Budget:** Supporter studies do not require a full study budget. Only the BIG network fee is due.

**BIG Sponsored studies**
Certain academic studies may be sponsored by BIG. These are limited to research programmes that do not involve an investigational product and are developed by BIG HQ on behalf of the BIG Executive Board and the network or studies for which no BIG member group is interested in serving as sponsor. These studies are run according to the principles of Lead or Co-Lead studies.

2.3.5  Participation in BIG studies

In principle, any member group of BIG may participate in a BIG trial. However, in some cases restrictions may apply: for example, a group that is an "adherent member" (rather than a full member) in BIG may be asked to participate only in trials with close monitoring; in other cases, the sponsor/ study funder may decide not to run a study in a particular country or region.

2.3.6  Discussion by the BIG scientific community

1. All concepts or ideas for new studies must be sent to the BIG Executive Board. The BIG Executive Board will evaluate the proposals and, if they agree, they will approve the study to be presented at one of the BIG scientific meetings.
2. Depending on who developed the concept for a new study, the presentation at the BIG Scientific Meeting can be done by a BIG Executive Board member, group representative or an individual researcher. However, individual researchers must inform the BIG Member Group with which they are affiliated before presenting the new study concept.

3. The presenter should contact BIG HQ in order to book a presentation slot at a BIG scientific meeting (held twice a year). In addition, the presenter should be prepared to provide to BIG HQ brief background information (e.g., study synopsis and information about planned financial and other support) for circulation to participants before the meeting, as well as slides for presentation during the meeting.

4. To benefit fully from the expertise and potential of the BIG network, ideally trials should be presented at BIG meetings while in the early concept stage, rather than as fully developed protocols or already running trials with little room for scientific discussion. However, it is acknowledged that many Supporter Trials will represent an exception to this principle. Presentation at a BIG scientific meeting allows for open discussion that can contribute greatly to developing both the optimal design as well as other aspects of the study. It can also help determine whether potentially competing studies exist or are in development by other BIG member groups. In the latter case, it may be possible for the groups to join forces to jointly run a trial. Finally, the presentation and discussion at a BIG scientific meeting will give the presenter an initial indication of whether other BIG groups have an interest in the study.

5. Collaboration may also be sought for trials involving the North American Breast Cancer Group or other North American academic groups. The principles described in this document will also apply for such a study to become a BIG trial.

2.3.7 Confidentiality
1. It is essential for BIG members to respect the confidentiality and intellectual property rights associated with new concepts presented at BIG scientific meetings. As a general principle, new ideas presented at such meetings remain with the group / investigator presenting the concept, and cannot be exploited by other BIG members / BIG HQ without agreement from the original proposer. The minutes of the BIG scientific meetings provide evidence of who presented a new project first.

2. Any documents provided to attendees at BIG scientific meetings or circulated to groups for consideration are confidential and should be clearly marked as such.

2.3.8 Interest of other BIG Member Groups to participate
1. During the BIG scientific meeting, potential interest from BIG member groups to participate in a particular study will be assessed.

2. If there is indication of potential interest in the study by BIG member groups, BIG HQ will assign a BIG number to the study and conduct a Group Interest Survey within the BIG network to formally assess the interest. This survey will be developed with input from the study proposer / group (and if appropriate the pharmaceutical partner/sponsor).

3. The study proposer/group must provide BIG HQ with a synopsis and, if not available, a study outline suitable for survey purposes. This outline should include at least the study rationale, study design, and information about sponsor and financial or other support (e.g., level of investigator fee, group fee, provision of study drug).
4. The study proposer/group provides BIG HQ with any restrictions that may apply for participation (see section 2.3.5 above).

5. BIG HQ will collect the responses to the Group Interest Survey and report back to the proposer/group.

6. BIG groups may follow their own internal procedures to determine group interest; however, to be considered for participation in a study, groups must abide by the survey timelines and discuss any deviations with BIG HQ.

7. Groups not interested in a study must also inform BIG HQ via the study survey.

2.3.9 Approval of BIG studies
When more than one group has confirmed interest to participate in the study, the BIG Executive Board will take a final decision about whether a trial should run under the BIG umbrella, and whether the proposed Leading Group is equipped to coordinate the trial in a multi-national setting. This decision will be documented in the Executive Board meeting minutes and will confirm the BIG study model that will be followed for the study.

2.3.10 Use of logos and study numbers
The BIG logo and study number should always be added to any documents where the logo and study number of the other partners is used (e.g., in study related documents, correspondence, communications, presentations and publications).
2.3.11 Flow chart

Start

Study proposal submitted to BIG EB for evaluation

Study presented at a BIG Scientific Meeting

Interest

No interest

Assign BIG study number
Preparation of Group Interest Survey by BIG HQ

Collection of survey results by BIG HQ

Interest

No interest

Proposal to BIG Executive Board for review & approval

Approval

Approval with comments

Disapproval

Set up of the study by BIG HQ and BIG group(s) that developed the proposal

Launch as BIG trial

End
2.4 Anti-Bribery & Anti-Corruption (Policy LEG-07)

2.4.1 Introduction
BIG is an international non-profit organisation for academic breast cancer research groups from around the world. BIG’s mission is to facilitate and accelerate breast cancer research at the international level by stimulating cooperation between its member groups and other academic networks, and collaborating with, but working independently from, the pharmaceutical industry.

To achieve this mission, BIG is committed to conducting all of its activities in an honest and ethical manner, and to act professionally, fairly and with integrity in its relationships with individuals and entities.

This policy sets forth the anti-bribery and anti-corruption principles BIG abides by.

2.4.2 Purpose and Scope
This Policy applies to all BIG Executive Board (EB) members, BIG Headquarters (HQ) Staff, Voting Representatives of BIG Member Groups, BIG Study Principal Investigators, BIG designated Advisors, or any others designated as a (co)-Chair or member of a BIG working group, task force or committee, subcontractors, consultants and any other individual persons and bodies associated or working with BIG and involved in BIG activities through a contractual relationship (collectively referred to as “Addressees” for the purposes of this Policy).

The Policy may not apply in case the Addressee has an ABAC Policy in place that it abides by, in which case the interested parties shall identify which policy applies to their interactions.

The purpose of this Policy is to outline BIG’s position on bribery and corruption and to provide information and guidance to those working for and with BIG.

The conflict of interest related aspects are governed separately by the Conflict of Interest Policy POL BIG-03.

2.4.3 Definitions
Bribery is an inducement or reward offered in order to gain any commercial, contractual, regulatory or personal advantage. Bribery can take variety of forms and covers anything of value, including cash, gifts, services, job offers, loans, travel expenses, entertainment or hospitality.

Corruption is the misuse of public office or power for private gain, or the misuse of private power in relation to business outside the realm of government. No bribes of any sort may be paid or accepted from customers, suppliers, politicians, government advisors or representatives of a private person of a company.

Gifts are benefits of any kind given voluntarily without expectation of receiving anything in return, as a sign of appreciation or friendship or to honour an occasion. They include courtesy gifts, which are small gifts given at culturally recognized occasions (e.g. weddings, funerals, retirements) or special times of the year (e.g. Christmas, New Year).

Facilitation payments are payments to public officials to expedite the performance of duties of a non-discretionary nature. These payments are intended to secure or influence the timing of the public officials’ actions (e.g. payments to expedite visa issuance or obtain an authorization).
2.4.4 General Principles

Within the context of a study, and as a general principle, BIG abides by the Anti-Bribery and Anti-Corruption Policy (ABAC Policy) provided by the sponsor of the study (either pharmaceutical company or academic group), and with whom BIG partners for the conduct of the study.

Should no ABAC Policy be mandated by the sponsor, the principles and rules of the following policy, developed hereunder, shall apply.

Within the context of a Supporter Model study, BIG shall comply with the ABAC policy of the leading group or any other ABAC policy identified as applicable by the leading group and/or its partner(s).

Within the context of non-study related activities, the present ABAC policy shall apply unless the Addressee(s) has/have an ABAC Policy in place that it/they abides by, in which case the interested parties shall identify which policy applies to their interactions.

BIG and the Addressees do not bribe and do not use intermediaries, such as agents, consultants, advisers, distributors or any other business partners to commit acts of bribery and this regardless of the status of the recipient (public officials or private persons). Should a considered action be viewed or potentially perceived as having an illegitimate purpose, BIG and the Addressee(s) must not proceed.

2.4.5 Gifts, Hospitality and Entertainment

Expenses incurred for travel, meals and accommodation by the individuals travelling on BIG’s account within the framework of a (Co-)Lead Model clinical study are governed by the study-specific travel policy developed for each trial.

Expenses incurred for travel, meals and accommodation by individuals travelling on BIG’s account for any non-study related purpose are governed by BIG’s Travel Policy, BIG-04. In particular, each policy includes maximum rates for hotel room accommodation, restrictions for air fare allowances, and specifies which costs are not reimbursable (such as personal expenses made during the travel, spouse/companion travel costs, …).}

Gifts and entertainment offered to third party(-ies) must be modest, reasonable and infrequent, in so far as any individual recipient is concerned. They must never be offered or provided with the intent of causing the recipient to do something favouring BIG or the Addressee or to refrain from doing something disadvantageous to BIG or the Addressee.

Cash and cash equivalents (e.g. shopping coupons) must never be given. Entertainment to a participant to BIG business meetings, congresses or comparable events must never be offered, unless the entertainment is an appropriate and incidental part of such events. Any side or extended trips may never be paid by BIG. Entertainment must never be paid and a gift never be offered to anyone who accompanies an invitee to a BIG business meeting, congress or comparable event.

In determining whether a gift or entertainment is ‘acceptable’, it should be looked at the intent behind it, and whether the publication of such gift or entertainment would cause embarrassment to BIG or the recipient.

Some circumstances permit to offer gifts or entertainment to third party(-ies):
- occasional meals with someone with whom BIG does business;
- occasional attendances at cultural and social events;
- gifts of nominal value, such as small promotional items.

2.4.6 Public Officials
Public officials (i.e. anyone in a position of official authority that is conferred by a state, including, in some countries, doctors, pharmacists, clinical trial investigators and nurses working at a government-owned hospital) are often subject to rules and restrictions that do not apply to persons who operate in the private sector. As a consequence, any relationship with public officials must be in strict compliance with the rules and regulations to which they are subject (i.e. any applicable rules or regulations in the particular country relating to public officials or that have been imposed by their employer) and any benefit conveyed to a public official must be fully transparent, properly documented and accounted for.

2.4.7 Facilitation Payments
BIG prohibits facilitation payments, irrespective of whether or not local law permits facilitation payments.

2.4.8 Payments to Third Parties and transparency reporting
BIG will only engage third parties if there is a legitimate need for the services they provide, and if there is a written contract or other written document with similar legal effect. Payment of third parties, including healthcare professionals (HCP) or healthcare organisations (HCO), can only be done after approval of invoices following delivery of services. No cash payments will be made. Payments shall be made or received in the country in which the entity or the person with which BIG transacts is resident and in the currency agreed in the contract. Payments are not made to or received from unrelated third parties or countries. Further details of such transactions are provided in response to legitimate requests (e.g. internal or external auditors, regulators and government officials).

Transparency reporting. For clinical studies where the sponsor is a pharmaceutical company, and also for academically sponsored studies receiving a grant from a pharmaceutical company, BIG shall collaborate with the pharmaceutical companies with regard to requests for transparency reporting about the transfer of value from pharmaceutical companies to healthcare professionals or healthcare organisations to fulfil the European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code, the US Physicians Payments Sunshine Act or any other official reporting requirements.

2.4.9 Business documentation and financial records
All BIG’s financial books and records accurately reflect and disclose the business rationale, purpose, substance and legality of all source of revenues, BIG local and cross-border transactions, payments and expenses.

The preparation and maintenance of BIG’s books and records must be consistent with applicable laws and regulations.
2.5 Data Privacy (Policy LEG-06)

2.5.1 Introduction
Breast International Group (“BIG”) has as its mission to support and initiate global collaboration to make significant advances in breast cancer research, reduce unnecessary duplication of effort, share data and enable collaboration of scientists across borders, contribute to the faster development of better treatments, and increase the likelihood of cures for patients.

Within the framework of these activities, BIG HQ collects various categories of Personal Data, required for the good conduct of such activities. BIG HQ understands that protecting the privacy of the patients and its partners is crucial. Therefore, BIG HQ strives to collect, store, use, disclose and process Personal Data in a manner that is consistent with the laws and regulations of the countries where it operates and its own ethical standards. In addition, BIG HQ strives to protect the rights of each individual whose Personal Data are being collected and further processed.

This policy establishes the process for BIG HQ to obtain, use and transfer Personal Data of individuals whose Personal Data are processed by BIG HQ in the context of a study or BIG scientific activities. It also aims to inform employees, group members and service providers of BIG about individuals’ rights and the rules to comply with in order to protect Personal Data.

2.5.2 Scope
This Policy applies to the Processing of Personal Data of individuals whose Personal Data are processed by BIG HQ in the context of a study or BIG’s scientific activities, including:

- Individuals participating in BIG studies as study subjects;
- Members of BIG studies’ governing committees;
- Investigators, researchers and staff members of institutions conducting research in the context of BIG studies

The collection and processing of Personal Data collected from individuals by BIG as an association and employer will be the object of an update to this policy.

Each employee, group member or service provider of and contracting with BIG HQ is required to comply with this Policy. In case national laws and regulations impose less stringent obligations for Processing Personal Data than provided by this Policy, this Policy shall serve to supplement such laws and regulations. Where national laws and regulations contain more detailed or stricter requirements than imposed by this Policy, the employees, group members and service providers of BIG HQ shall comply with such laws and regulations. When it acts as a Data Controller, BIG shall make all required notifications to the competent national data protection authorities or obtain the appropriate authorizations regarding its Processing of Personal Data, as required by applicable data protection laws and regulations.

2.5.3 Definitions
Personal Data means any information relating to an identified or identifiable natural person. This includes for example names, gender, date of birth, place of birth, personal postal address, e-mail address, telephone number, photograph, nationality, driving license number, passport number.

Processing means any operation or set of operations which is performed on Personal Data or on sets of Personal Data, whether or not by automated means, such as the collection,
recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

**Sensitive Personal Data** means Personal Data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, as well as genetic data, biometric data, data concerning health, data concerning a natural person's sex life or sexual orientation and Personal Data relating to criminal convictions and offences.

**Data Controller** means the natural or legal person, public authority, agency or other body which alone or jointly with others, determine the purposes and means of the data Processing.

**Data Processor** means the natural or legal person, authority, agency or other body which processes Personal Data on behalf of the Data Controller.

### 2.5.4 Data Protection Principles

When Processing Personal Data, the following data protection principles shall be complied with:

**Lawfulness, fairness and transparency.** Personal Data must be processed lawfully, fairly and in a transparent manner.

**Purpose Limitation.** Personal Data must only be used for one or more specified, explicit and legitimate purposes and must not be used in any way which conflicts with those purposes.

**Data Minimization.** Personal Data must be adequate, relevant and not excessive in relation to the purposes for which they are collected and further processed.

**Accuracy.** Personal Data must be accurate and kept up to date.

**Storage Limitation.** Personal Data must be kept for no longer than necessary for the purposes for which the Personal Data are originally collected, except where Personal Data are processed solely for scientific purposes, subject to the implementation of appropriate measures to safeguard Personal Data and individuals’ rights.

**Integrity and Confidentiality.** Appropriate security measures must be implemented to protect Personal Data, including against unauthorized or unlawful Processing, accidental loss, destruction or damage.

### 2.5.5 Personal Data We Collect

BIG HQ, contracted group members or contracted service providers collect the following categories of Personal Data:

- **Clinical trial subjects:** Processing of Sensitive Personal Data about the individuals who take part in clinical trials.
- **Health care professionals (HCP):** Processing of Personal Data related to HCP and staff of such HCP in the hospitals and clinics that take part in a clinical study, represent a BIG group within BIG or participate in BIG scientific activities;
- **Members of BIG studies’ governing committees:** Processing of Personal Data related to members of BIG studies’ governing committees (e.g. Independent Data Monitoring Committee, Steering Committee, etc.);

Individuals shall be informed about the data Processing purposes, when feasible, at the time of the Personal Data collection. In addition, where employees, contracted group members or
contracted service providers of BIG HQ intend to process Personal Data for another purpose than for which Personal Data was originally collected, individuals must be informed about that other purpose (unless falling under the exceptions granted by laws).

Personal Data and Sensitive Personal Data shall only be processed lawfully, i.e., to the extent that one of the following legal bases apply:

- The individual has given his or her consent to the Processing of his or her Personal Data for one or more specified purpose;
- The individual has given his or her explicit consent to the Processing of his or her Sensitive Personal Data for one or more specified purpose; or
- The Processing is necessary for scientific research purposes.

When collecting Personal Data as well as Sensitive Personal Data, individuals shall be informed about the identity of the Data Controller, its contact details and the contact details of the data protection officer, if any.

The Sensitive Personal Data collected from clinical trial subjects include health-related data. To enhance privacy, consistent with ICH-GCP, patient names and other direct identifiers are not collected and linked to records or samples collected for research purposes. Instead, clinical trial subjects are only identified by a code.

The Personal Data collected from HCPs and Members of BIG studies’ governing committees may include:

- Identity information including name, gender, place and date of birth, personal postal address, e-mail address, telephone number, photograph, nationality, passport number,
- Personal details including marital status, dependent information, dietary restrictions,
- Employment information including employment title, degree, professional qualifications, professional commitments, education and work history,
- Financial information including personal and professional bank account information, financial interests.

2.5.6 Use of Personal Data

Sensitive Personal Data may only be processed for specified, explicit and legitimate purposes which include:

- Tracking clinical trial subjects’ enrolment and follow-up and performing data and biomedical sample analysis in BIG clinical studies;
- Conducting BIG clinical studies, answering the scientific questions raised through BIG clinical studies, supporting required administrative steps for commercialization of an invention, molecule, or biomarker;
- Use for further translational research projects conducted within the context of BIG studies.

Personal Data may only be processed for specified, explicit and legitimate purposes which include, but are not limited to:

- Inviting potential HCPs to apply to participate in BIG scientific activities;
- Managing BIG sites and BIG groups participating in BIG studies;
• Managing the conduct of BIG clinical studies and research activities;
• Set-up and management of BIG studies’ governing committees;
• Managing the conduct of translational research within the context of BIG studies;
• Managing and defining BIG’s scientific missions and objectives;
• Organizing scientific meetings.

2.5.7 Data Retention Period
Sensitive Personal Data must only be retained for the duration of the study, including translational research, or research program, or for a longer period in accordance with applicable law and the consent given by the study participant, provided that appropriate technical and organizational measures are implemented to protect Sensitive Personal Data.

Personal Data must only be retained according to purpose and applicable law, provided that appropriate technical and organizational measures are implemented to protect Personal Data.

Individuals will be informed regarding the period for which the (Sensitive) Personal Data will be stored where feasible, at the time of the Personal Data collection.

2.5.8 Individual’s Rights
Individuals have certain rights with respect to their (Sensitive) Personal Data, including:
• The right to receive certain minimum information with respect to the Processing of their Personal Data, including the identity and contact details of the Data Controller and data protection officer, if any; the purposes and legal bases for the Processing; the applicable data retention period; information as to whether Personal Data is required or optional and any consequence due to failure to reply; information regarding their rights; information regarding the existence of automated decision-making; and where Processing is based on consent, information about how to withdraw such consent (“right to transparency”);
• The right to request access to Personal Data held about them (“right of access”);
• The right to request that Personal Data held about them are rectified or erased, or that access to such Personal Data is restricted (“right to rectification, right to restriction and right to erasure”);
• The right to object to the Processing of their Personal Data (“right to object”);
• Subject to certain conditions, the right to request that their Personal Data, which they provided to a Data Controller, are sent to them in a structured, commonly used and machine-readable format and transmitted to another Data Controller (“right to data portability”) and
• Where Personal Data are subject to transfers to a third country, the right to be informed about the appropriate safeguards that have been implemented to protect such Personal Data.
• Where (Sensitive) Personal Data are processed for scientific research purposes and the exercise of the right to erasure is likely to render impossible or seriously impair the achievement of the objectives of such Processing, such right may be limited.
BIG strives to respect individuals’ rights when Processing (Sensitive) Personal Data. Accordingly, any individual’s request must be handled in compliance with applicable regulatory requirements, without undue delay and at the latest within one month.

2.5.9 Appropriate Safeguards, Data Security and Personal Data Breach

Appropriate technical and organizational measures must be implemented to protect (Sensitive) Personal Data, including administrative, technical and physical security measures. In addition, appropriate measures must be implemented to prevent data loss, theft, misuse, unauthorized access, modification, disclosure or destruction.

Sensitive Personal Data from clinical studies which are stored in special web-based program managed by third party subcontracted by BIG are only accessible to authorized personnel on a need to know basis.

Subcontracts with third parties in charge of data management on behalf of BIG include provisions in order to guarantee respect of data protection laws and regulations and principles stated in the BIG Data Privacy Policy.

Likewise, each employee, group member contracted by or service provider contracted by BIG HQ shall ensure privacy, accuracy and update of (Sensitive) Personal Data.

Each employee, group member or service provider of BIG HQ must immediately report a (potential) data breach to its superiors or representatives. BIG HQ shall take all appropriate measures to notify the data breach to national data protection authorities or the affected individuals, where applicable.

2.5.10 Sharing of Personal Data

(Sensitive) Personal Data may be disclosed to third parties (including hospitals, research groups, data centers, investigators, laboratories, study governing committees, ethical committees, monitors, regulatory authorities, sponsor in connection with the above-mentioned purposes, where consent –or explicit– consent of the individual has been collected. Third parties who receive (Sensitive) Personal Data are required to guarantee protection of such (Sensitive) Personal Data, in compliance with the requirements laid down by applicable data protection laws and regulations, including security requirements, and the present Policy.

2.5.11 International Data Transfers

(Sensitive) Personal Data may be transferred to group members or service providers of BIG located in other European Member States as well as in third countries including in, but not limited to, Argentina, Australia, Bosnia & Herzegovina, Brazil, Canada, Chile, China, Colombia, Cuba, Ecuador, Egypt, El Salvador, Guatemala, Hong-Kong, India, Iran, Israel, Japan, Jordan, Korea, Mexico, Montenegro, New Zealand, Nicaragua, Norway, Pakistan, Panama, Peru, Russia, Serbia, Singapore, South Africa, Taiwan, Turkey, United States, Uruguay and Venezuela in connection with the above-mentioned purposes. The laws of these third countries may not provide adequate protection for (Sensitive) Personal Data according to the European Commission. In these circumstances, appropriate safeguards must be implemented (including the execution of Standard Contractual Clauses) or, in absence of appropriate safeguards, the individual’s explicit consent to the transfer must be collected, as part of the consent obtained for participation in the clinical study.
2.6 Travel and Expenses (Policy BIG-04)

2.6.1 Introduction
BIG is an international non-profit organisation for academic breast cancer research groups from around the world. BIG’s mission is to facilitate and accelerate breast cancer research at the international level by stimulating cooperation between its member groups and other academic networks.

This policy describes the principles on hospitality and procedures for reimbursement of expenses made when traveling on BIG’s account.

2.6.2 Scope
This policy applies to all individuals (employees and non-employees) travelling on BIG’s account and for whom travel has received prior approval by the employee’s line manager or BIG Headquarters’ (HQ) CEO for non-employees.

For the principles on Gifts and Entertainment, refer to policy LEG-07.

For the principles and procedures for reimbursement of expenses made when traveling on BIG’s account in the framework of a (Co-)Lead Model clinical study, refer to the study-specific travel policy.

2.6.3 General principles
Travelers may only claim expenses related to the travel period not already covered by another party. For example, if the traveler attends a BIG-organized meeting during a conference that s/he would attend even if the BIG-organized meeting in question did not take place, it is assumed that the traveler’s expenses will be covered by another party and not by BIG.

Individuals will organize their own travel, including accommodation if required, unless instructed otherwise by BIG HQ.

To receive reimbursement, the request must be submitted to BIG HQ within forty-five (45) working days of the meeting, together with all supporting documents, i.e. a duly completed reimbursement form (Form BIG-04.1), accompanying original receipts, and, if applicable, the exchange rate used together with a copy of that rate on a website such as Oanda. In principle, requests for reimbursement submitted during a fiscal year other than the year when the expenses were made will not be reimbursed, except for travel made in the last month of the fiscal year on the condition that the request for reimbursement is made within forty-five (45) working days of the travel.

For healthcare professionals reimbursed for travel expenses in the context of BIG studies sponsored by/receiving a grant from a pharmaceutical company, BIG HQ shall collaborate with the pharmaceutical companies for transparency reporting about the transfer of value from pharmaceutical companies to healthcare professionals (Policy LEG-07).

2.6.4 Air travel
• Arrangements should be made on a “lowest logical” airfare basis. To obtain the lowest possible prices, reservations must be made, normally in economy (coach) class (or an
“economy plus” equivalent for a flight duration of 6 hours or more), as soon as participation in a meeting is confirmed.

- Any business class travel must receive prior approval by BIG HQ. If this has not been the case, BIG will only reimburse the cost for economy class.
- Penalty charges for lost tickets, cancellations or last-minute changes must receive prior approval by BIG HQ. If this is not the case, BIG will not reimburse these charges.
- Receipt of air travel must be attached to the travel reimbursement form. The most common receipts are the boarding pass and agency invoices. Airline e-ticket receipts are accepted; however, the passenger’s name must be clearly legible.

### 2.6.5 Ground Transportation

- Train travel will be economy (second) class. First class travel must receive prior approval by BIG HQ.
- It is expected that each traveler will use the best means of traveling to and from the airport or other destination related to the meeting at hand, taking into consideration cost, time and transport availability. Please make use of available public transportation, airport shuttle buses, or local taxi service.
- Taxi expenses must be itemized on the travel reimbursement form with the details of the date, reason, names of the traveler(s), and must be accompanied by a receipt.
- Use of private car (e.g., from home to the airport) will be reimbursed according to the kilometer rate provided by the Belgian tax authorities, as indicated on Form BIG-04.1.
- In general, car rental will not be approved, unless warranted under exceptional circumstances. Such rental must receive prior approval from BIG HQ.
- Parking expenses may be reimbursed if paid parking is the most reasonable option for a meeting at hand.
- Any long-term parking (e.g., more than one day at airport garage) must receive prior approval by BIG HQ.

### 2.6.6 Accommodation

- Hotels of choice are those that offer reasonable, economical business services.
- The maximum reimbursable standard single room nightly rate, before taxes, is 150-200 EUR in Europe and 200-300 USD in the US, or comparable equivalents adapted to local standards in other regions of the world. For nightly rates exceeding these, upfront approval is to be obtained from BIG HQ.
- Penalty charges for all cancellations or last minute changes must receive prior approval by BIG HQ.
- The number of nights to be reimbursed by BIG must be communicated to BIG HQ prior to the meeting. Note that BIG will only reimburse the number of nights needed to attend a meeting or meetings (approved by BIG HQ). Let’s take the example of person who was planning to attend ASCO and normally would travel on 31 May to attend the conference only. The costs to attend the conference, including airfare and hotel costs, will be covered by his/her institution. If BIG organizes a meeting that takes place on 31 May, requiring the individual to travel one day earlier, BIG will reimburse the additional night’s accommodation needed, but not the remaining nights. If no request was made prior to the meeting, BIG retains the right to refuse some costs.
- Laundry services, mini bar (with the exception of water), in-room movies and other personal expenses (e.g. health club fees) will not be reimbursed by BIG.
2.6.7 Meals

- Reasonable expenses for meals and refreshment may be reimbursed at the discretion of BIG HQ. It is expected that travelers will choose restaurants good value for money. BIG HQ reserves the right to reject expenses deemed excessive (e.g. luxury restaurants)
- Personal meals are non-reimbursable if a BIG hosted meal is foreseen (i.e. if lunch is provided for a BIG meeting on a particular day, the traveler cannot also claim lunch for the same day). Employees will not receive luncheon vouchers for the days they are traveling.

2.6.8 Non-Reimbursable Expenses

The following list of non-reimbursable expenses are provided as a guidance and not limited to the following:

- Spouse/companion travel expenses
- Personal phone calls
- Magazines, books …
- Personal articles or personal care costs
- Alcohol (except as reasonable accompaniment to a meal or business meeting)
- Exchange commission charges

Please note that all other expenses not included in this guideline must receive prior approval by BIG HQ.

2.6.9 Procedure for Reimbursement

Reimbursements will be made within 30 days of receipt of a duly completed travel reimbursement form (Form BIG-04.1) and all supporting original invoices/receipt (evidence) for each expense, with date and amount clearly indicated.

Payments will be made in EUR, but can also be done in another currency if clearly specified on the travel reimbursement form.

The reimbursement form, duly completed, and supporting original documentation should be addressed to:

Breast International Group (BIG)-aisbl
Attn: Finance Department
76 Blvd. de Waterloo
B-1000 Brussels, Belgium
accounting@bigagainstbc.org
3. Who is who

3.1 Executive board

Current Board effective from 1 Jul 2017:

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3.2 BIG HQ Organization

Current detailed organigrams can be provided to members upon request.