



Policy BIG-01

Vision, Mission and Principles of Research Conduct

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Version:	3.0 - Final
Date:	19 Apr 2021
Effective Date:	19 Apr 2021

This version replaces all previous versions as of the Effective Date

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1. INTRODUCTION

BIG's Vision and Mission Statement

The Breast International Group (BIG) is an independent international non-profit umbrella organization for academic breast cancer research groups from around the world. We expect our members to share the principle of conducting breast cancer research that is scientifically independent and not motivated by personal profit, meaning that any surplus from BIG's or its member groups' research must be reinvested into breast cancer research. BIG's vision is to cure breast cancer through global research and collaboration; its mission is to facilitate breast cancer research internationally

BIG provides a forum for its Member groups to:

- combine resources and expertise to conduct research to advance knowledge of the disease and to optimally serve patients;
- establish clinical and translational research priorities;
- reduce the unnecessary duplication of efforts;
- obtain study results quickly;
- collaborate with other scientific networks;
- develop models of collaboration with the pharmaceutical and biotechnology industry that preserve scientific independence.

The updated version of the vision and mission statement, and the principles of research conduct have been approved by the General Assembly, and are an appendix to the BIG Articles of Incorporation / "statutes".

2. SCOPE

This policy applies to BIG members and their representatives, Executive Board members, Advisors, and BIG Headquarters staff.

3. POLICY

1. Research conducted under the umbrella of BIG serves to advance knowledge about breast cancer in order to improve treatments and outcomes for patients.
2. BIG studies may be sponsored by a BIG member group, sponsored by BIG for specific research programmes, or sponsored by a pharmaceutical/biotechnology industry partner. Irrespective of sponsorship and funding model BIG's scientific independence from industry is maintained. BIG does not function as a contract research organization, nor does it carry out studies solely conceived by industry. All studies are developed and conducted with substantial input from BIG investigators and leadership and aim to answer potentially practice-changing clinical questions essential for improving and saving lives of breast cancer patients.

3. “Independent from industry” means that a BIG Member group, affiliated trials units, or BIG HQ for specific research programmes shall control the main study (clinical) database. Industry partners may access the full study data at the earliest after a database lock and under specific conditions ensuring that no influence may be exerted on the analysis process or in the presentation of the data to the study Steering Committee (SC). In addition, including for studies sponsored by industry, all statistical analyses and study reports related to a BIG study shall be executed or supervised by one or more statisticians who are members of BIG groups or affiliated trials units or are otherwise academic collaborators of BIG, but who are independent from the major funding body for the study.
4. Each study shall have a SC that is representative of the groups and centres participating in the study. Industry collaborators may be represented on the SC but shall neither hold a majority of seats, nor have the power of veto.
5. The SC of large studies, registration studies and those using treatments with potential safety concerns shall be advised by an IDMC, the members of which may neither participate in the study, nor represent the sponsor(s).
6. Study monitoring may be conducted in part or exclusively by industry partners but must involve supervision by the BIG group or trials unit coordinating the study. Other study activities may also be delegated to other collaborators of BIG, including commercial partners as appropriate, but this will always be done under the supervision of one or more of the academic study partners.
7. The study SC shall be responsible for publications & presentations, which shall follow accepted scientific practice, academic standards, the study protocol, and any specific guidelines established by the SC for the study.
8. All BIG studies shall follow Good Clinical Practice guidelines and any applicable laws.
9. Access to and use of biological samples collected in the context of research conducted under BIG shall be governed by policies approved by the study SC and any applicable laws.
10. In consideration of the importance of long-term efficacy and safety evaluations, BIG strongly endorses the long-term follow-up of patients participating in clinical studies.

In the interest of maintaining healthy partnerships between academia and industry, preserving BIG’s scientific independence, and developing research in the best interest of patients with breast cancer, BIG members and their representatives, Executive Board members, Advisors, and BIG Headquarters staff agree to abide by BIG’s statutes, Code of Conduct (BIG-19), and Conflict of Interest (BIG-03) or any other policies approved by the General Assembly.

4. INTERNAL REFERENCES

BIG Articles of Incorporation / “statutes”

Policy BIG-03 “Conflict of Interest and Financial Disclosure Policy”

Policy BIG-19 “Code of Conduct”

5. CHANGE HISTORY

New version	Effective Date	Significant Changes
01.0 / 01-Dec-2009	01-Dec-2009	Initial Policy
01.1 / 06-Jul-2011	06-Jul-2011	Updated BIG logo inserted; minor wording changes pursuant to BIG EB Retreat 2010 (reduce <i>unnecessary</i> duplication; obtain study results <i>efficiently</i>)
01.2 / 11-Mar-2014	11-Mar-2014	New BIG logo inserted
01.3 / 17-Jun-2014	17-Jun-2014	Updated Mission Statement inserted
2.0 / 03-Feb-2021	03-Feb-2021	Addition of vision statement, scenario of academic sponsorship, and scenario of running research programs in addition to clinical studies
3.0 / 19-Apr-2021	19-Apr-2021	Clarification of timepoint and conditions for access to the full study data by industry partners.