BIG Mission and Principles of Research Conduct

DOCUMENT HISTORY

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11.03.2014	BIG HQ	v01.2	New BIG logo inserted
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BIG Mission and Principles of Research Conduct

1. What is BIG's Mission?

The Breast International Group (BIG) is an international non-profit umbrella organization and legal entity for academic breast cancer research groups from around the world, dedicated to facilitating 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.

When conducting or participating in clinical trials or research programs under the BIG umbrella, BIG Members agree to adhere to the following Principles of Research Conduct:

1.1. Research conducted under the umbrella of BIG serves to advance knowledge about breast cancer in order to improve treatments and outcomes for patients.

1.2. All BIG trials shall remain independent from the pharmaceutical / biotechnology industry, even if they are sponsored wholly or in part by industry.

1.3. "Independent from industry" means that a BIG Member group or affiliated trials unit shall control the database, and that industry partners may access the full trial data only after its release by the Steering Committee (SC) for the trial, and the Independent Data Monitoring Committee (IDMC). In addition, all statistical analyses and study reports related to a BIG trial shall be executed or supervised by one or more statisticians who are members of BIG groups or trials units or are otherwise academic collaborators of BIG, but who are independent from the major funding body for the trial.

1.4. Each trial shall have a SC that is representative of the groups and centers participating in the trial. Industry collaborators may be represented on the SC, but shall neither hold the majority of seats, nor have the power of veto.

1.5. The SC of large trials, registration trials and those using treatments with potential safety concerns shall be advised by an IDMC, the members of which may neither participate in the trial, nor represent the sponsor(s).

1.6. Trial monitoring may be conducted in part or exclusively by industry partners, but must involve supervision by the BIG group or trials unit coordinating the trial.

1.7. The trial 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 trial.

1.8. All BIG trials shall follow Good Clinical Practice guidelines and any applicable laws.

1.9. Access to and use of biological samples collected in the context of research conducted under BIG shall be governed by policies approved by the trial SC and any applicable laws.

1.10. In consideration of the importance of long-term efficacy and safety evaluations, BIG strongly endorses the long-term follow-up of patients participating in randomized clinical trials.

2. BIG's Relationship to the Pharmaceutical / Biotechnology Industry

The BIG Principles of Research Conduct govern the relationship between BIG and the pharmaceutical / biotechnology industry for the conduct of BIG trials, regardless of whether the sponsor of an individual trial is an industry partner or a BIG group.

BIG's research principles and the scientific and clinical trials expertise offered by BIG members and its Headquarters take into account both the requirements of industry (e.g., provision of data necessary for registration) and academia (e.g., answers to critical scientific questions; long-term follow-up of patients; integration of the latest technologies and translational research into clinical trial designs, including the prospective collection of biological materials…). This way, BIG and its members remain responsible for determining the research priorities, controlling the data and deciding when and where research findings (positive and negative) should be presented and published.

The respect for these key principles by all partners involved has allowed BIG to develop and coordinate breast cancer trials in a healthy partnership between academic groups and industry, while preserving BIG's scientific independence from industry.

3. The Benefits of Collaboration under the BIG Umbrella

This unique form of collaboration under the BIG umbrella offers a win-win situation for all the partners involved. It contributes to the faster development of effective treatments, and ultimately better treatments and the higher likelihood of cures for patients.

3.1. Benefits to BIG members

The benefits to individual research groups of collaboration with BIG as an association with a central HQ structure to collaborative research include, but are not limited to:

- The possibility to discuss research issues with breast cancer opinion leaders from over 40 different research groups, spread over the different continents;
- Access to promising new drugs;
- Faster accrual, especially in niche patient populations and, thus, faster answers to the study questions;
- The potential to change medical practice by working within a large academic network and together with, but scientifically independent from, industry partners that can deliver new drugs to the market;
- Potential participation in cutting-edge translational research related to BIG trials, including access to biological specimens on a competitive, peer-reviewed basis;
- Access to BIG know-how for the conduct of large global trials and registration trials;
- Linking to other important stakeholders in the research process (e.g., patient advocate networks, cancer societies).

Members can also access BIG Headquarters services such as the following:

- Support for the planning and organization of meetings and arrangements for presenting at BIG scientific meetings;
- Support for taskforces and committees, including related guidelines;
- Access to a communications infrastructure supporting BIG research activities (e.g., *BIG Newsletter*, website, E-update; information at BIG booth during major breast cancer conferences);
- Support for contracts and general trial budgets, including templates, negotiations and general advice.

3.2. Benefits to industry

The creative partnership with industry that BIG has developed over recent years provides industry with unique benefits. These include, but are not limited to:

- Access to a broad, well-established network of highly qualified academic research groups and their members, namely, investigators and specialized hospitals and research centres from around the world;
- Input from internationally renowned opinion leaders in breast cancer research
- Expertise in clinical trial design, conduct and analyses;
- Scientific credibility by having the study conducted independently, with the collection, management and analysis of data firmly in the hands of a BIG collaborative group;
- Strict academic rules that also meet all industry requirements for drug registration.

3.3. Benefits to patients and the wider community

The benefits from research conducted under the BIG umbrella for patients and the wider community include, but are not limited to:

- The credibility and scientific integrity needed to “keep faith” with the many patients who volunteer to participate in BIG trials;
- Reducing the wasteful duplication of effort and obtaining research results more quickly through BIG’s approach to creating synergies and facilitating partnerships between its members and other networks in the cancer research community
- Contributing to the faster development of effective treatments, and ultimately better outcomes for patients and, therefore, the wider community.