

## MISSION STATEMENT

The Breast International Group (BIG)-aisbl is a non-profit organisation dedicated to facilitating breast cancer research internationally. It 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 duplication of efforts
- obtain study results quickly
- collaborate with other scientific networks, and
- develop models of collaboration with the pharmaceutical and biotechnology industry that preserve scientific independence.

BIG members adhere to the following principles of research conduct:

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. All BIG trials shall remain independent from the pharmaceutical / biotechnology industry, even if they are sponsored wholly or in part by industry.
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 BIG trials shall be executed or supervised by a statistician, who may be a member of the BIG group or trials unit responsible for the trial, but who is independent of any other funding partners involved in the study.
4. Each trial shall have a SC that is representative of the groups and centres 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.
5. The SCs 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 industry sponsor(s).
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.
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.
8. All BIG trials 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 trial 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 randomised clinical trials.