



International Breast Cancer Study Group

MEMORANDUM

TO: Anita Hiltbrunner
Director, International Breast Cancer Study Group (IBCSG)

FROM: Daniel Hayes, MD
Chair, IBCSG Data and Safety Monitoring Committee
Laura Cava Northrop, DSMC Coordinator

DATE: November 22, 2016

RE: IBCSG Data and Safety Monitoring Committee Recommendations

CC: Drs. Prue Francis, Gini Fleming, Olivia Pagani, Barbara Walley, Alessandra Gennari, Guy Jerusalem, Sherene Loi, Fabrice André, Ann Partridge, Luca Malorni, Dimitrios Zardavas, Meredith Regan, Elisabetta Munzone

This memorandum summarizes the recommendations of the IBCSG Data and Safety Monitoring Committee (DSMC), which met on November 7, 2016, to conduct a regularly scheduled semi-annual review of interim clinical and safety data of IBCSG-coordinated trials. This memorandum should be posted on the IBCSG website. It is the responsibility of the principal investigator to relay this information to his or her local ethics committees and to collaborating investigators at all sites.

The DSMC is an independent committee of scientific, clinical and biostatistical experts as well as a patient representative. The DSMC Coordinator, Laura Northrop; the IBCSG Group Statistician Meredith Regan; the IBCSG Statistical and Data Management Center Director, Richard Gelber; and other staff from the IBCSG Statistical Center attend meetings as non-voting members.

The DSMC's primary charge is to ensure that studies are conducted in a manner that does not expose participants to undue risk.

IBCSG Trial (name)	Data Reviewed	Recommendation
24-02 (SOFT)	Adverse events (AEs), second (non-breast) malignancies, deaths without prior cancer event	Continue follow-up as planned
25-02 (TEXT)	AEs, second (non-breast) malignancies, deaths without prior cancer event	Continue follow-up as planned
35-07 (SOLE)	AEs, second (non-breast) malignancies, deaths	Continue follow-up as planned
41-13 (TREND)	Accrual, AEs, serum sample collection	Continue as planned
42-12 (SNAP)	Treatment, AEs, deaths	Continue trial closure and follow-up as planned
45-13 (PANACEA)	Accrual, treatment, AEs, conduct	Continue as planned
48-14 (POSITIVE)	Accrual, safety	Continue as planned
53-14 (PYTHIA)	Accrual, design, treatment	Implement plans to drop placebo control and continue with single arm palbociclib+fulvestrant
54-16 (METEORA)	Design, treatment	Continue as planned