

Principles of Data Sharing

Breast Cancer Trials is committed to the principle of sharing outputs from its research, including publications and data, as per the NHMRC Open Access Policy and other applicable international guidance. Responsibly sharing trial data can help advance research and improve outcomes for patients.

Collaboration with commercial companies is not excluded. BCT Members/Institutions who receive data to conduct approved research projects must adhere to the same ethical standards as BCT.

Where intellectual property may arise from research, intellectual property rights will generally remain with BCT and any financial gain will be reinvested in BCT research. Specific details regarding intellectual property rights will be specified in the relevant Data Sharing Agreement.

Data from BCT trials are managed under the direction of the BCT Board of Directors, BCT Scientific Advisory Committee (SAC), and relevant committees, including the Trial Steering Committees relevant to the trial data.

Review of applications

Data requestors will be required to submit a research proposal, along with the BCT Data Request Application (contact concept@bctrials.org.au to obtain this form), to document the acceptability of the research question and the qualifications of the requestor(s). Research proposals will include:

- Qualifications and experience of the proposed research team
- A description of the data being requested
- The hypothesis to be tested
- The rationale for the proposed research
- The statistical analysis plan
- A publication plan
- A description of any potential conflicts of interest, including potential competitive use of the data
- The source of any research funding.

BCT Operational Executive (Director of Research/SAC Chair or designee, SAC Deputy Chair, Chief Executive Officer, Chief Operating Officer - Research) will appraise the scientific value and the priority of proposed research projects and determine the proper use of data.

Ethics and peer review

Applications must include a commitment to obtain appropriate Human Research Ethics Committee approval for research on data provided from BCT-sponsored trials.

Scope of Data

In general, data will be made available for request after publication of the main/final study results.

Additional circumstances that may prevent BCT from sharing requested data:

- Data for the trial is not owned by BCT

- It may be difficult to ensure protection of the privacy and confidentiality of research participants e.g. small studies (less than 50 participants), single-centre studies, studies terminated early for lack of enrolment, or studies for which data does not exist in a format that can be readily anonymised
- Clinical data that have been collected subject to legal, contractual or consent provisions that prohibit transfer to third parties
- Informed consent may not allow for data sharing
- Case narratives, documentation for adjudication, imaging data (e.g. x-rays, MRI scans, etc.), genetic data and exploratory biomarker data
- Substantial practical constraints to providing access to the data e.g. older, pre-electronic data for which files cannot be located, size and complexity of databases, or resources required to retrieve data from repositories and redact personally identifiable information from relevant documents.

Anonymisation of Data

Protecting the privacy of patients who participate in clinical trials is an important obligation of sponsors who conduct clinical trials and therefore BCT will take appropriate measure, including pseudo-anonymisation of data, to ensure that patient privacy is safeguarded.

BCT Data Sharing Agreement

The Chief Investigator(s) of the proposed research project and/or head of any research facility to which data is provided must sign a Data Sharing Agreement stating the terms and conditions for accessing the data.

All publications arising from Data Sharing projects from BCT-sponsored trials will follow the BCT Publication Guidelines.

The Chief Investigator(s) of the project must:

- Sign the Data Sharing Agreement and agree not to distribute the shared data or information to parties not identified in the research application, use the data for purposes not contained in the application, or seek to re-identify research participants
- Meet costs involved in extracting data from the clinical trial database
- Submit an annual report on the project for the Operational Executive (every 12 months from Data Sharing Agreement execution)
- Notify BCT of project completion and appropriate destruction of data (as per the Data Sharing Agreement)
- Ensure BCT is acknowledged in any resulting publications, in addition to any BCT members who fulfil authorship criteria for the project
- Submit a copy of published data to BCT.