



International Breast Cancer Study Group

IBCSG



ETOP·IBCSG
PARTNERS

International Breast Cancer Study Group

Data Sharing Policy for IBCSG Trials

Table of Contents

1. Introduction.....	2
2. Procedures for Requesting Shared Individual-Patient Data (IPD)	2
3. Regulatory Considerations	3
4. Conditions for Data Sharing	4
5. Fees	4
6. Appeals Process.....	4
7. Contacting IBCSG.....	4

Current version: [21 December 2022]

Revised: [25 May 2022]

First approved by IBCSG Scientific Executive Committee (no longer exists): 8 October 2016

Current version approved by IBCSG Scientific Committee Co-Chairs: Marco Colleoni (Chair), Sherene Loi (Co-Chair)

For questions or comments contact the IBCSG Statistical Center (stat_center@ibcsg.org).



ETOP IBCSG Partners Foundation

Effingerstrasse 33 · 3008 Bern · Switzerland · +41 31 511 94 00 · TRIALSNAME@etop.ibcsg.org · www.etop.ibcsg.org

1. Introduction

This document describes the Data Sharing Policy for IBCSG trials. The Policy is in compliance with the National Institutes of Health (NIH) Final Statement on Sharing Research Data, released February 26, 2003 (NIH Notice: NOT-OD-03-032), and the International Committee of Medical Journal Editors (ICMJE) requirements for sharing clinical data.

This Policy does not state legal requirements regarding patients and/or third parties. Rather, all concrete activities regarding (contractual) relationships with patients and/or third parties shall be lawful.

Each IBCSG study has a formal protocol document, which includes a statement of the objectives of the study. Patient consent is obtained to collect the individual patient data required for addressing the study objectives. Data from study forms are sent from the treating or enrolling institution to the IBCSG Statistical and Data Management Centers (SDMC), where it is processed, entered into the IBCSG database, and validated. The electronic database is used as the basis for the analysis of IBCSG studies, with the analyses performed by the IBCSG SDMC.

This Policy pertains only to breast trials sponsored by the ETOP IBCSG Partners Foundation. It includes trials in which other cooperative groups may enroll patients. It does not pertain to trials in which IBCSG is a participating group only, i.e. trials coordinated by another group.

The procedures described here do not cover requests from national health authorities for information required by regulations or by the terms of grant awards. Such requests do not require internal review or approval, and will be honored as expeditiously as possible.

This document also does not cover requests for collection of additional data. Requests for additional data may require obtaining additional patient consent and/or authorization. Consequently, the information obtained is often incomplete. Retrospective collection of data is expensive and time consuming and therefore rare.

Only requests for data collected and stored in the IBCSG trial database are covered by this Policy. Requests for use of tissue and/or other biospecimens have a separate review procedure managed by the IBCSG Translational Research Working Group (TRWG). Information about the IBCSG Tissue Bank and TRWG Policies and Procedures are available at www.ibcsg.org.

2. Procedures for Requesting Shared Individual-Patient Data (IPD)

While most analyses of IBCSG trials are performed at the IBCSG Statistical Center, IBCSG also makes clinical trial data available to investigators who wish to receive IPD from one or more IBCSG trials. The investigator must make a formal request, which is reviewed by the IBCSG Scientific Committee Chairs and other relevant committees. The scientific merit and feasibility of each request will be evaluated, as well as the cost and priority with regard to all IBCSG research. Approval is subject to the availability of IBCSG Statistical Center staff and resources.

If the trial is a Co-Lead model (e.g. BIG-ETOP IBCSG Partners Foundation Co-Lead), the Data Sharing Policy should be in agreement with the other Group's Data Sharing Policy.

Requests will only be considered once the primary trial analyses have been published. Any release of data will take into consideration individual patients' rights to privacy as described in the patient informed consent document.

2.1. Requests from Statistical Centers of Participating Cooperative Groups for IPD from Patients Enrolled by the Requesting Group Only

These requests for IPD from a subgroup enrolled by a participating group are automatically honored, and no special approval is required, although a brief proposal (approximately 2 pages) indicating the project objectives and analysis plan must be submitted to the IBCSG Group Statistician.

2.2. Requests for IPD for Research Projects or Meta-Analyses

The IBCSG may share IPD with participating investigators and other investigators who submit sound scientific proposals in accordance with the *Guidelines for Collaborative Research for IBCSG trials*, available at: www.ibcsg.org.

2.3. Requests for IPD to Illustrate Statistical Methodology

The IBCSG may share IPD with statistical researchers who submit sound scientific proposals in accordance with the *Guidelines for Collaborative Research for IBCSG trials*, available at: www.ibcsg.org.

2.4. Pharmaceutical Companies

IPD may be provided to pharmaceutical companies, but generally for regulatory rather than research purposes. If a contract has been executed covering the request, further review is not required. Data may also be made available to pharmaceutical companies for other, clearly stated purposes, with the approval of the ETOP IBCSG Partners Foundation Director and eventually the Foundation Board if appropriate, e.g. in case of commercial use of data. The approval will be dependent on whether additional funding is required and the terms of the respective contracts.

2.5. Sharing Data in Journal Repositories

Some journals require or strongly encourage that IPD used for a journal article be deposited in an open-access repository. IBCSG does not support such open-access repository, but encourages requesting IPD as per procedures outlined in this Data Sharing Policy.

3. Regulatory Considerations

All IBCSG clinical trials are conducted in compliance with national health authority laws and regulations. Research use of data collected on human subjects from IBCSG studies is subject to group guidelines and applicable laws and regulations in the country of origin.

The IBCSG informed consent forms starting in 2016 state: Individual patient data may be shared with qualified researchers for approved sound scientific proposals in accordance with Guidelines for Collaborative Research for IBCSG trials.

4. Conditions for Data Sharing

Release of data for research purposes is subject to the following conditions. ETOP IBCSG Partners Foundation requires a signed “Data Transfer Agreement” and a supplemental “Data Processing Agreement.” A template is available in the *IBCSG Guidelines for Collaborative Research*, available at: www.ibcsg.org.

- Investigators must agree to use the data only for the approved research project. If the investigator later wishes to use the data in a new project, a new proposal must be submitted.
- Investigators must implement appropriate technical and organizational measures to ensure data protection requirements. In particular, investigators must agree to keep the individual patient data confidential and may not be transferred to third parties. The data may only be shared within the team conducting the analysis project. Requests from other individuals for access to the data should be referred to IBCSG.
- The regulatory requirements noted in Section 3 must be met.
- Applicable fees must be paid (See Section 5).
- Copies of all manuscripts arising from the project must be sent to the IBCSG prior to submission, with an opportunity for the IBCSG to provide comments prior to submission.
- There is no expectation of IBCSG representation on the authorship unless members of IBCSG have made substantial contributions to the project. See ETOP IBCSG Partners Foundation Guidelines for Publications and Presentations for IBCSG trials for authorship guidelines, available at: www.ibcsg.org.
- Release of data collected in a clinical trial conducted under a binding collaborative agreement between the ETOP IBCSG Partners Foundation and a pharmaceutical/biotechnology company must be in compliance with the terms of the binding collaborative agreement and must be approved by IBCSG and the company. Release of the data is also subject to the terms of any contracts between ETOP IBCSG Partners Foundation and other entities, which cover any of the requested data.
- In releasing the data, the Group makes no representations and extends no warranties of any kind, either expressed or implied. There are no expressed or implied warranties of merchantability or fitness for a particular purpose, or that the use of the data will not infringe any patent, copyright, trademark, or other proprietary rights. No indemnification for any loss, claim, damage, or liability will be intended or provided.

5. Fees

Fees may be charged for preparing and documenting the requested data set. Fees will be limited to the actual time, effort, and materials required for preparing and documenting the data set. Fees are determined on a case-by-case basis.

6. Appeals Process

If a request for data is denied, the applicant may appeal the decision. The appeal will be reviewed by the Director or his/her designee in conjunction with an ad hoc committee comprised of IBCSG Scientific Committee members.

7. Contacting IBCSG

For questions or comments contact the IBCSG Statistical Center (stat_center@ibcsg.org).