Canadian Cancer Trials Group

Data Management & Sharing Plan

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1 Introduction

The Canadian Cancer Trials Group is committed to making the results and outputs of research available through effective and efficient data management and data sharing practices. CCTG recognizes that the individual patient data (IPD) from its trials represent a rich resource and is committed to supporting their use for purposes that extend beyond the purposes defined in trial protocols. Consequently, when CCTG led studies are published, a statement that IPD data will be shared when feasible after formal application is made.

IPD for CCTG led NCTN trials supported by the Cancer Therapy Evaluation Program of the National Cancer Institute are posted at the NCI and accessible there and adhere to all NIH policy requirements.

Databases for other CCTG led trials are housed at CCTG.

Investigators external to the CCTG operations and statistical office can use CCTG IPD for research projects via two mechanisms: 1. Undertaking an analysis of data that remains at CCTG via collaborative project with CCTG faculty; 2. Requesting that trial data be released for analysis at the investigator's institution. This policy applies to both mechanisms. It describes the process for making a request, as well how requests are evaluated, which are the same in both cases. The additional steps required when data is to be released are also described.

2 Acronyms and Definitions

CCTG	Canadian Cancer Trials Group
ICMJE	International Committee of Medical Journal Editors
NCI	National Cancer Institute
CTEP	Cancer Therapies Evaluation Program
IPD	Individual Patient Data
SOP	Standard Operating Procedure

For the purposes of the Datasharing and Access Policy, terms are defined as follows:

- **Scientific Data:** The recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data do not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens.
- **Data Management:** The process of validating, organizing, protecting, maintaining, and processing scientific data to ensure the accessibility, reliability, and quality of the scientific data for its users.
- **Data Sharing:** The act of making scientific data available for use by others (e.g., the larger research community, institutions, the broader public), for example, via an established repository.
- **Metadata:** Data that provide additional information intended to make scientific data interpretable and reusable (e.g., date, independent sample and variable construction and description, methodology, data provenance, data transformations, any intermediate or descriptive observational variables).

- **Data Management and Sharing Plan (Plan):** A plan describing the data management, preservation, and sharing of scientific data and accompanying metadata.

3 Data Type, Tools/Software/Code, and Data Standards

A. CCTG clinical trials generate IPD which includes demographic, treatment, laboratory, safety, patient reported and efficacy outcomes. Selective trials may also include data from the analysis of biospecimens.
B. These scientific data are preserved in the trial database. The database includes baseline and on protocol specified demographic, treatment, laboratory, safety, patient reported and efficacy outcomes. Patient identifiers are removed for datasets that are shared.
C. Metadata, other relevant data and associated documentation include protocol and trial documents, case report forms and data dictionaries.
D. CCTG trial databases and analyses are done with SAS software. CCTG uses NCI Common Data Elements for its NCI trials and CDISC data formats.
E. Data in limited types of formats (SAS, Excel, STDM), data dictionaries, data identifiers, definitions, unique identifiers, and other data documentation are provided for each trial.

4 Data Preservation, Access, and Associated Timelines

The databases of CCTG led trials are housed at CCTG. Currently, IPD from trials led by CCTG supported by the Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute (NCI) are posted at the NCI and accessible there and covered by US NCI CTEP policies.

When CCTG led studies are published, a statement that IPD data will be shared when feasible, where the data are available and how to access the data will be included in the publication. Investigators external to the CCTG operations and statistical office can use CCTG IPD for research projects via two mechanisms: 1. Undertaking an analysis of data that remains at CCTG via collaborative project with CCTG faculty; 2. Requesting that trial data be released for analysis at the investigator's institution.

CCTG Clinical Trial Data will be made available to the research community as soon as possible but no later than within one year of the completion of acceptance of the data for publication, submission to a public clinical trial registry such as clinicaltrials.gov or public disclosure of a submitted patent application, or review by a regulatory authority whichever is earlier. Trial databases and trial related documents are preserved a minimum of 25 years and may be longer as determined by interest, use and ability to preserve the database.

5 Access, Distribution, or Reuse Considerations

Access, distribution, or reuse of scientific data related to CCTG trial datasets are determined by the following factors

- Informed consent
- Privacy and confidentiality protections consistent with applicable federal, Tribal, provincial/state, and local laws, regulations, and policies
- Access to scientific data derived from humans will be controlled via review by CCTG or (as applicable) by NCI.
- Restrictions imposed by federal, Tribal, or state laws, regulations, or policies,
- Existing or anticipated agreements

Requests for Genomic Data will be assessed based on CCTG Genomic Data Policy.

6 Oversight of Data Management and Sharing

Compliance with the DMS Plan will be monitored and managed, by the Group Chair, Chief Operations Officer, Group Biostatician and Chief Information Systems and Technology Officer at the CCTG Operations and Statistical Centre, Queen's University. Data sharing requests and outcomes will be monitored at least annually and as needed to assess alignment of requests and their execution with policy, to ensure quality, timeliness and adequacy of resources for datasharing.

7 Request Procedure

An investigator who wishes to use IPD from one or more of the CCTG's studies must make a formal request to the CCTG. The CCTG will review the request as described below. Requests for data will only be considered once the primary study analyses have been published. If the investigator wishes to discuss the request before filing a formal application, they should contact the relevant study senior investigator or, for a multiple study request they should contact CCTG Senior investigators involved in the studies and/or relevant CCTG scientific committee.

CCTG has developed a platform accessible from its website for submitting, processing, evaluating, and tracking data use requests.

CCTG will conduct a review of the merit and feasibility of the proposal, including whether there are sufficient available data to provide adequate information for analysis., The initial review will be conducted by the relevant study statistician(s) and senior investigator(s). If they have concerns about the scientific merit or feasibility of the proposal, additional faculty and members of the appropriate Disease Site Committee(s) may be consulted for further input on required scientific content or feasibility. In addition, Senior Managers will be consulted if the proposal represents additional workload or other feasibility concerns. Once a proposal is approved on scientific grounds, the budget and logistic issues will be considered. Investigators will be notified of the CCTG's decisions in writing by the Senior Investigator and/or Senior Biostatistician. If a request is denied, the CCTG will, in the written decision, state the reasons the request was denied and inform the investigators that a denied request may be appealed as outlined below. This information will also be tracked.

8 Regulatory Issues

This policy aligns with CCTG policies for Privacy and Confidentiality (CTG-POL-0009), Clinical Data Transfers (DBS-SOP-0116), and Informed Consent (ERG-SOP-0069) and is in accordance with applicable regulations and guidelines. The working assumption of this policy is that the analyses described will be conducted using de-identified data. CCTG will assess the need for REB approval and re-consent where applicable. This assessment takes into account TCPS 2 which states that "consent is not required for research that relies exclusively on secondary use of non-identifiable information."

9 Release Conditions and Disclaimer

In circumstances where, for whatever reason, it is decided that data should be released rather than analyzed “in house”, the release of data is subject, but not limited, to the following conditions. A formal data use agreement covering the relevant conditions will be required.

- 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 cite the trial identifier and source of data, in publications and presentations
- The investigator must agree to keep the IPD confidential. 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 the CCTG.
- The investigator must agree to not to attempt to identify study participants, must agree to to destroy the data after analyses are completed, to not redistribute of the data to third.
- The regulatory requirements discussed below must be met.
- A fee may be charged, using a cost recovery model, to support the internal infrastructure required to assemble the requested datasets.
- CCTG policies will apply to the use and transfer of data including but not limited to CCTG policies for Privacy and Confidentiality (CTG-POL-0009), Clinical Data Transfers (DBS-SOP-0116), and Informed Consent (ERG-SOP-0069). If data are being provided for an independent project, then there may be no expectation for the CCTG to have representation on the authorship; where CCTG members have made substantial contributions to the project, authorship will be expected. Details of authorship must be negotiated prior to CCTG release of data and will be included in the data sharing agreement
- A contract between CCTG and the relevant parties regarding the release of data will be executed. The release of data collected in a clinical trial conducted under a binding collaborative agreement between the CCTG and NCI/CTEP must be in compliance with the terms of the collaborative agreement between CCTG and NCI/CTEP. Release of data collected in a clinical trial conducted under a binding collaborative agreement between the CCTG and a pharmaceutical / biotechnology company must be in compliance with the terms of the binding collaborative agreement and must be approved by CCTG and the company. Release of the data is also subject to the terms of any contracts between CCTG and other entities, which cover any of the requested data.

10 Appeal Process

If a request for data is denied the applicant may appeal the decision. The appeal will be reviewed by the Chair of the CCTG in conjunction with the Group Biostatistician and an ad hoc committee of the CCTG’s Clinical Trials Committee. Where applicable, the appeal review process will also include the NCI’s program officer and an outside statistician. The statistician will be named jointly by the CCTG Chair and the program officer.

11 Revision History

Version Number	Version Date	Brief Description of Revision(s)
V001	March 25, 2016	Draft
V002	July 20, 2016	Initial Release
V003	March 5th, 2017	Updated to clarify that this is now the CCTG Policy for Data Sharing and Access. CTG-POL-0008 Data Sharing is now obsolete.
V004	November 30, 2020	Updated to reflect new process via DASH system.
V005	January 29th, 2025	Full SOP Review. Updates made to align with the new NIH Policy effective Jan 25th, 2023. Changes included insertion of Definitions and new sections 3, 4, 5, 6, and 9.
V006	February 12th 2025	Updated title of policy.

12 Signature

Signature of Responsible Group Leader:	Janet Dancey	On file	Feb 12, 2025
	Name	Signature	Date