

Policy Statement



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Undertaking Secondary Analysis on Data from TROG Trials

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Summary: This policy statement covers the considerations necessary for facilitation, approval, access, review and publication of secondary analyses from TROG trials.

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Applies to: Trial Chairs and TMCs developing a TROG trials and any researcher wishing to use TROG data for analysis (member or non-member)

Approved by: TROG Scientific Committee (TSC) Chair

Revision Chronology: Vs 1; 09 Sep 2011 New Policy

Vs 2; 18 Jul 2013 Annual review

Vs 3; 08 Feb 2018 Changes requested by TSC and Secondary Data Analysis Committee (SDAC).

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1 BACKGROUND

Considerable resources are required to undertake a clinical trial. Those resources can be utilised to collect sufficient data to extend the impact of the trial beyond its original primary question, facilitating ad hoc secondary analyses.

Many secondary analysis questions are posed during or subsequent to completion of the trial and involve collaborators who are not part of the original investigator team

The TROG trials portfolio is constantly growing and the datasets (database and DICOM files) are increasing in size and maturity, therefore there is a need to facilitate access for secondary analysis.

Both TROG members and non-members may make an application to the TROG Scientific Committee (TSC) for access to data sets held by TROG for this purpose. All applications are to be supported by a full TROG member.

2 SCOPE

This document covers the considerations necessary for approval, access, review and publication of secondary analyses.

3 APPLICATION PROCESS

A formal proposal for access to data will be made to the TROG Scientific Committee (TSC), which may consult with the TROG Secondary Data Analysis Committee (SDAC). The proposal must have sufficient detail to ascertain the purpose of the study, the specific data required (including formats), access methods and analysis plan.

Please see appendix 1 for the 'Secondary Analysis Proposal' form, which includes all components needed for the TSC to make their decision.

- 3.1 The TSC and SDAC will consider the scientific value of the proposal and will seek the advice and agreement of the relevant Trial Chair and/or Trial Management Committee (TMC).

The TSC and SDAC may also request an expert review if appropriate.

If the analysis crosses several trials, agreement from each applicable Trial Chair and/or TMC will be sought.

The trial Chairs or TMCs should not unreasonably withhold permission to use data for a secondary analysis.

If the proposed secondary analysis involves re-analysis of the original data, then the primary statistician is to be consulted.

- 3.2 Access to a dataset for secondary analysis may only be endorsed under the following circumstances:

- a. When the primary analysis has been completed and published
OR
- b. Where the secondary analysis will have no impact on the analysis and publication of the primary endpoint
OR

- c. When the Trial Chair agrees to release the dataset before primary analysis and publication, after endorsement by the TSC.

NB: Endorsement by the Independent Data Monitoring Committee (IDMC) is needed if circumstances b and c.

- 3.3 The authorship and intellectual property details must be agreed between the Trial Chair/TMC and the Proponent of the secondary analysis before approval will be given.
- 3.4 The TSC, TMC or Trial Chair approve, request amendment or reject the proposal. The TSC will notify the Proponent via a formal letter of the decision.

4 APPROVAL and DATA ACQUISITION

- 4.1 Approved secondary analyses will be given a TROG tracking number.
- 4.2 The study will be entered on the TROG Trial Tracking log and the progress regularly monitored by the TSC until publication. Study updates may be requested of the Proponent at the discretion of the TSC.
- 4.3 The study protocol (and any amendments) is to be submitted to the TSC for approval before being submitted to any regulatory or ethical review committees.
- 4.4 The Proponent must forward copies of all regulatory and/or ethical approvals to TROG Central Operation Office.
- 4.5 The data will transferred to the Proponent from the Trial Coordinating Centre (TCC) where the trial database is maintained.

The data is to be transferred in a secure way and in a format agreed upon by the Trial Chair and the Proponent.

The TCC is to inform TROG Central Operations Office when the data transferred occurred and what data was sent, for recording in the Secondary Analysis Tracking sheet.

5 PUBLICATION

- 5.1 The Trial Chair of the primary study should generally be included as an author on the ensuing publication(s).
- 5.2 Publication generally must not occur before publication of the definitive paper describing the primary outcomes. A request for a variation from this would require approval by the TSC and Trial Chairs.
- 5.3 Draft publication(s) must be submitted for review to the TROG Publications Committee prior to submission to a journal. Any publications should follow TROG *Authorship Publication and Spokesperson Guideline*.

Secondary Analysis Proposal



The TROG Scientific Committee will review this proposal and will request clarification and/or provide feedback as soon as possible.

Submission details

Date of submission:

Full Trial Title:

Trial acronym:

Phase: ☐ II ☐ III ☐ Other, specify

Name of Proponent:

Institution:

Phone:

E-mail address:

Data required from TROG Trial: **TROG** ☐☐.☐☐

TROG Member Supporter:

Rationale:

Hypothesis(es) to be tested:

Endpoints:

Statistical Considerations/Analysis Plan:

Proposed Timeframe:

Data Requirements:

Means of Access:

Personnel Involved:

Proposed amount and source of funding (please attach a copy of any applications submitted):

Does this proposal require additional HREC approval and/or consent of the participants?

References: