



Trans Tasman Radiation Oncology
Group Limited
ACN 132 672 292

TROG POLICY STATEMENT

Guidelines for Statistical Support for TROG Trials

TPS E11

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(Always refer to the TROG website to check for the current version of this policy)

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1. The Role of the Statistician in Clinical Trials

According to the ICH guideline Statistical Principles for Clinical Trials (E9)¹ “the actual responsibility for all statistical work associated with clinical trials will lie with an appropriately qualified and experienced statistician, as indicated in ICH E6 (GCP Guidelines²). The role and responsibility of the trial statistician, in collaboration with other clinical trial professionals, is to ensure that statistical principles are applied appropriately in clinical trials supporting drug development. Thus, the trial statistician should have a combination of education/training and experience sufficient to implement the principles articulated in this guidance.”

The trial statistician contributes to the design, the conduct, and the analysis and interpretation of a clinical trial. It is important that a dedicated trial statistician be involved from the inception of the trial. A trial statistician must be an active member of the Trial Management Committee (TMC) as described in the TROG Policy Statement ‘Responsibilities of Trial Management Committees’.

Therefore, the purpose of these guidelines, designed to assist the TROG Scientific Committee, is to ensure that statistical support is provided by a person or persons with adequate, relevant qualifications and experience in clinical trials.

2. Qualifications and Experience

2.1 TROG Requirements

The statistician assigned to a TROG trial must either be:

- a. A suitably qualified and experienced independent statistician; i.e.:
 - i. Possess adequate qualifications – AStat accreditation (as accredited by the Statistical Society of Australia) or equivalent; and
 - ii. Have had adequate experience in providing independent statistical support of clinical trials.

OR

- b. A suitably qualified statistician in an established, recognised clinical trials centre; i.e.:
 - i. The trials centre is either the Biostatistics and Clinical Trials Centre (BaCT), Peter MacCallum Cancer Centre or the NHMRC Clinical Trials Centre (CTC), University of Sydney or equivalent; and
 - ii. Have available adequate statistical supervision and back-up for the trial; and

- iii. Have GStat accreditation (as accredited by the Statistical Society of Australia) or equivalent.

Desirable criteria: It is desirable for the statistician to have prior *oncology* trial experience but not mandatory.

2.1.1 Statistical Society of Australia Accreditation³

2.1.1.1 Criteria for Accreditation as AStat

Accreditation as an Accredited Statistician is based on a combination of formal qualifications in statistics, relevant practical experience and demonstration of professional competence. At the time of application for accreditation, candidates must be actively involved in the practice of statistics. Holders of the Accredited Statistician qualification must meet at least one of the following requirements.

1. A pass degree of equivalent with a Statistics component equivalent to that of second or third level Statistics subjects or Mathematics majors in Australian universities, plus six years practical experience in applying statistics;

OR

2. A first or second class honours degree or equivalent in Statistics or in a subject containing substantial coverage of statistical methods or theory, plus four years practical experience in applying Statistics;

Graduate Diplomas in Statistics, depending on their origin, may fulfil the degree requirement under one or other of the above two categories. In the course requirements in 1. or 2. above, the Accreditation Committee shall judge the acceptability of the standard and level. Under exceptional circumstances applicants may be accredited who do not fulfil either of the degree requirements above, but who can demonstrate both

- a breadth of knowledge and understanding of both theoretical and applied Statistics equivalent to at least the degree requirement of the second category above, and
- at least ten years practical experience applying statistics.

2.1.1.2 Criteria for Accreditation as GStat

Holders of the qualification of Graduate Statistician shall meet at least the degree requirement of 1. above, provided no more than eight years have elapsed since the award of the degree or equivalent of requirement 2.

3. TROG Statistical Support Review Committee

3.1 Composition and Responsibilities

The SSRC will consist of the TROG Statistician, TROG Scientific Committee (TSC) Chair (who will also act as SSRC Chair) and the Trials Development Portfolio Chair.

The TROG Statistical Support Review Committee (SSRC) will be responsible for ensuring that all statisticians working on TROG-led trials meet the requirements as detailed in 2.1 above. This will be achieved by reviewing the CVs and other supporting documentation such as proof of adequate statistical supervision and back-up for the trial (where required – see 2.1 b).

3.2 Process - Trials Under Development

The Trial Chair is responsible for providing the statistician's contact details to the TROG Central Operations Office (TCOO) as soon as the statistician has been proposed by the Trial Chair.

The TCOO will request the CV and supporting documentation from the statistician, and will then forward these details to the SSRC.

The SSRC may either:

- a) Approve the proposed statistician as Trial Statistician or
- b) Recommend that the proposed statistician take up the role of Trial Statistician but is supervised by a 'TROG Approved Statistician' or
- c) Recommend that the proposed statistician is not considered suitable at this point in time to act as a TROG Trial Statistician.

The Chair of the SSRC will write to the proposed statistician with the recommendation with a copy to the Trial Chair and TCOO.

3.3 Process - Current Trials

These guidelines will be applied to those trials approved for activation or open in the 12 months prior to guideline finalisation and assessed on a case by case basis.

3.4 Meetings

The SSRC may meet at in person or by teleconference. Alternatively, the review may be performed via email if the proposed statistician has already been involved in TROG trials and has previously met TROG statistical support requirements as outlined in 2.1 above. The review should occur no later than one month after receiving the statistician's CV. The SSRC should report on the status of the reviews to the TSC at the quarterly meetings.

4. TROG Approved Statisticians

TROG will be responsible for maintaining a list of Approved Statisticians for the purpose of:

- a) assisting Trial Chairs of Trials under Development to obtain a suitable trial statistician.
- b) for established, recognised clinical trials centres nominating an Approved Statistician to act in a supervisory role for 'junior' Trial Statisticians.

5. References

1. ICH Harmonized Tripartite Guideline: Statistical Principles for Clinical Trials (ICH E9). Available at: http://www.tga.gov.au/docs/html/euguide/euad_clin.htm#clinicalgeneral
2. Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) annotated with TGA comments, TGA, Australia, July 2000. Available at <http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf>
3. Available at <http://www.statsoc.org.au/what-is-professional-accreditation.htm> Accessed 8 September 2010.