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## Glossary of Terms

**Document Number:** TPS E1

**Version:** 3

**Effective date:** 06 December 2013

**Number of pages:** 18

**Summary:** This policy statement provides an alphabetised list of specialised terms used in Radiation Therapy Clinical trials along with their definitions

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**Applies to:** TROG full and affiliate and lifetime members, TROG staff

**Approved by:** TROG Scientific Committee

**Review date:** June 2014

**Revision Chronology:**

vs 1, 01 Sep 2008:	Original document
vs 2, 13 Nov 2009:	Addition of definitions for new treatments and techniques. Original definitions refined
vs 3, 06 Dec 2013:	Clarification of TROG trial development and conduct time point definitions. Original definitions further refined

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## DEFINITIONS

**Accrual:** The accumulation of trial participants registered on a clinical trial.

**Adverse Drug Reaction (ADR):** All noxious and unintended responses to a drug that occur at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease.

**Adverse Event (AE):** Any untoward medical occurrence in a patient or a clinical investigation subject. There may not necessarily be a causal relationship with an investigational treatment<sup>1</sup>.

**Annual General Meeting (AGM):** During the first quarter of each calendar year TROG convenes an Annual General Meeting (AGM) of its members for the purpose of conducting business-related activities. The AGM is held within the Annual Scientific Meeting.

**Annual Scientific Meeting (ASM):** During the first quarter of each calendar year TROG convenes an Annual Scientific Meeting (ASM) of its members for the purpose of receiving new trial proposals and monitoring ongoing TROG trials.

**Approved for Activation:** A phase within the lifecycle of a trial (i.e. concept to completion), which commences when a trial has met the TROG trial development milestones and is given permission to commence site activation processes. A TROG number will be allocated at the commencement of this phase.

**Approved for Development:** A phase within the lifecycle of a trial (i.e. concept to completion), which commences when a new proposal receives the endorsement of the TROG Membership at the TROG ASM and is approved for development by the TSC.

**Arm:** Any of the treatment groups in a randomised trial. Most randomised trials have two or more "arms"<sup>2</sup>.

**Audit:** A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data was recorded, analysed and accurately reported according to the protocol; sponsor's standard operating procedures; good clinical practice; and the applicable regulatory requirements<sup>1</sup>.

**Audit Trail:** Documentation that allows reconstruction of the course of events<sup>3</sup> (of the trial).

**Australian New Zealand Clinical Trials Registry (ANZCTR):** A publicly accessible online listing (register) of clinical trials being undertaken in Australia and New Zealand. Available at: <http://www.anzctr.org.au/about.aspx>

**Baseline:** The initial time point in a clinical trial, just before a trial participant starts to receive the treatment as per protocol<sup>2</sup>.

**Bias:** When a point of view prevents impartial judgment on issues relating to the subject of that point of view. Bias is controlled by blinding and randomisation<sup>2</sup>.

**Blind:** A randomised trial is "blind" if the trial participant is not told which arm of the trial he/she is on and is therefore unaware of whether he/she is in the experimental or control arm of the trial; also called masked<sup>2</sup>.

**Case Report Form (CRF):** A printed, optical or electronic document designed to record all information on each Trial Participant required by the Protocol.

**Central Trial Coordinator (CTC):** The Central Trial Coordinator is responsible for supervising the overall conduct and data management of the trial and is based at the Trial Coordinating Centre.

**Clinical Trial Agreement (CTA):** A written agreement between two parties that define the scope of work and formalise the understandings between the parties.

**Clinical Trial Notification (CTN):** The CTN Scheme is a *notification scheme* used for clinical trials involving any product not entered on the Australian Register of Therapeutic Goods (TGA); or use of a registered or listed product in a clinical trial beyond the conditions of its marketing approval<sup>4</sup>.

**Clinical Trial Exemption (CTX):** The CTX Scheme is an *approval process* used for clinical trials involving any product not entered on the Australian Register of Therapeutic Goods; or use of a registered or listed product in a clinical trial beyond the conditions of its marketing approval<sup>5</sup>.

**Clinical Trials Registry:** See: Australian New Zealand Clinical Trials Registry.

**Clinicaltrials.gov:** A clinical trials registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

**Closed to Accrual:** A phase within the lifecycle of a trial (i.e. concept to completion), which commences after the last participant has been recruited. During the closed phase, participants will complete follow up, the main analyses will occur and processes implemented to complete the trial.

**Collaborating Group:** A national and/or international clinical trials group that jointly undertakes a clinical trial with another group. See: Appendix 2.

**Completed:** A phase within the lifecycle of a trial (i.e. concept to completion) which commences after the final follow up has occurred, the main analysis has been performed and published; the trial database has been locked; trial sites have been closed; and records archived.

**Confidential Information:** Means all the information, forms, reports, ideas, concepts, technology, processes and Intellectual Property relating to the Trial and the Protocol including the Trial Database and all Trial Data (i.e. patient information).

**Control Group:** The standard by which experimental observations are evaluated. In many clinical trials, one group of trial participants will be given an experimental drug or treatment, while the control group is given a standard treatment for the illness<sup>2</sup>.

**Controlled Trials:** In a controlled clinical trial, the control group is a standard against which experimental observations may be evaluated. One group of trial participants is given an experimental drug, while the control group is given a standard treatment for the disease<sup>1</sup>.

**Data Integrity:** Attention to the consistency, accuracy and correctness of data stored in a database or other electronic file<sup>6</sup>.

**Data Management:** Tasks associated with the entry, transfer and/or preparation of source data and derived items for entry in a clinical trial database<sup>3</sup>.

**Data Manager (DM):** The person who is assigned to only perform activities associated with the day to day interpretation, management, operation and support of data including data entry and data querying. The DM is usually situated at the Trial Coordinating Centre.

**Data Quality:** Describes the characteristics that confirm “fitness for use”. That is, the ability to support meaningful and trustworthy conclusions and interpretations. Quality is established through formal assessment, quality control and auditing<sup>3</sup>.

**Data Query:** A request to an investigator, for clarification on a data item collected for a clinical trial, to resolve an error or inconsistency discovered during data review<sup>3</sup>.

**Data Query Management:** Ongoing process of data review, discrepancy generation, and resolving errors and inconsistencies that arise in the entry and transcription of clinical trial data<sup>3</sup>.

**Data Query Resolution:** The closure of a query usually based on information contained in a data clarification<sup>3</sup>.

**Database:** The electronic medium for the data storage needs of a specific Trial, which contains all information required to be collected as per the Protocol.

**Database Lock:** Means the time point at which the Trial Database is locked (data cannot be added or changed) for the purposes of analysis.

**Deaf:** The capitalised term ‘Deaf’ identifies persons who are classed as culturally and linguistically diverse and use a sign language, such as Auslan (Australian Sign Language), as a first or preferred language<sup>8</sup>.

**ECOG Performance Status:** Means the scales and criteria used by doctors and researchers to assess how a patient's disease is progressing; assess how the disease affects the daily living abilities of the patient; and determine appropriate treatment and prognosis<sup>9</sup>. Developed by the Eastern Cooperative Oncology Group (ECOG), Robert Comis M.D., Group Chair. Refer to: <http://ecog.dfci.harvard.edu/> for further information.

**Efficacy:** (Of a drug or treatment). The maximum ability of a drug or treatment to produce a result regardless of dosage. A drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed<sup>2</sup>.

**Eligible patient:** Means a patient selected in accordance with, and who meets, the eligibility criteria specified in the Protocol.

**Eligibility Criteria:** The clinical and demographic characteristics that define those participants eligible to be enrolled in the trial<sup>10</sup>.

**Empirical:** Based on experimental data, not on a theory<sup>2</sup>.

**Endpoint:** See: Outcome

**Enrolment:** The act of admitting a participant into a trial.

**Essential Documents:** Documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced<sup>1</sup>.

**Ethics Approval:** Approval given by a Human Research Ethics Committee (HREC) for a clinical trial to be conducted on human subjects.

**Follow-up:** A process of periodic contact with participants enrolled in a trial for the purpose of monitoring health status, administering trial treatments, modifying the course trial treatment, observing the effects of the trial treatment, or for data collection<sup>10</sup>.

**Good Clinical Practice (GCP):** A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate; and that the rights, integrity, and confidentiality of the trial participants are protected<sup>1</sup>.

**Human Research Ethics Committee (HREC):** An independent body, consisting of medical/scientific professionals and non-medical/non-scientific members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of the trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial participant<sup>1</sup>.

**Hypothesis:** In a trial, a statement relating to the possible different effect of the interventions on an outcome. The null hypothesis of no such effect is amenable to explicit statistical evaluation by a hypothesis test, which generates a P (i.e. probability) value<sup>10</sup>.

**Independent Data Safety Monitoring Committee (IDSMC):** A group of independent experts external to a trial assessing the progress, safety data and, if needed critical efficacy endpoints of a clinical trial<sup>7</sup>.

**ICH GCP Guidelines:** Means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Topic E6, Guidelines for Good Clinical Practice (CPMP/ICH/135/95) as adopted by the TGA.

Available at: <http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf>.

**ICH GCP Standards for Expedited Reporting:** Means the 'Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (CPMP/ICH/377/95)', which is an internationally accepted standard for the reporting of important clinical safety information principally arising during clinical development of medicines and any other applicable standards that may be developed from time to time.

Available at: <http://www.tga.gov.au/docs/pdf/euguide/ich/ich37795.pdf>

**International Conference on Harmonisation (ICH):** The International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) was established in 1990 as a joint regulatory/industry project to improve, through harmonisation, the efficiency of the process for developing and registering new medicinal products in Europe, Japan and the United States, in order to make these products available to patients with a minimum of delay. The six parties to ICH represent the regulatory bodies and research-based industry in the three regions—Europe, Japan and the USA—where the vast majority of new medicines are currently developed<sup>11</sup>.

**Inclusion/Exclusion Criteria:** The medical or social standards determining whether a person may or may not be allowed to enter a clinical trial. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history and other medical conditions. It is important to note that inclusion and exclusion criteria are not used to reject people personally, but rather to identify appropriate trial participants and keep them safe<sup>2</sup>.

**Informed Consent:** A process by which a patient voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the patient's decision to participate. Informed consent is documented by means of a written informed consent form (which has the name of the trial clearly displayed) which must be signed and dated by the trial participant (or the trial participant's legally acceptable representative) and the Investigator, in the presence of each other<sup>1</sup>.

**Institution:** The entity, through the Principal Investigator, which is responsible for the conduct of the Trial at the Trial Site(s).

**Institutional Review Board (IRB):** Term used in the United States to describe a Human Research Ethics Committee.

**Intellectual Property:** Means all inventions, trademarks, trade names, copyright, patents, registered designs, trade secrets and know-how and other intellectual property rights arising out of the performance of the Trial.

**Intergroup Trial:** A clinical trial supported by two or more collaborating clinical trials groups according to a single protocol. An Intergroup trial requires a Trial Coordinating Centre which will support the administrative requirements of the research and perform central data collection and analysis<sup>12</sup>.

**Interpreter:** A person who facilitates oral or sign language communication between two or more speakers who are not speaking (or signing) the same language.

**Intention-to-treat Analyses:** A strategy for analysing data in which all participants are included in the group to which they were assigned, whether or not they completed the intervention given to the group<sup>10</sup>.

**Interim Analysis:** Analysis comparing intervention groups at any time before the formal completion of the trial, usually before recruitment is complete. Often used with "stopping rules" so that a trial

can be stopped if participants are being put at risk unnecessarily. Timing and frequency of interim analyses should be specified in the protocol<sup>10</sup>.

**Investigators Brochure (IB):** An extensive summary of a research compound, including animal screening, preclinical toxicology, and detailed pharmaceutical data. Also included, if available, is a summary of current knowledge about pharmacology and mechanism of action and a full description of the clinical toxicities.

**Investigational Product:** Means, where relevant, any medicine or device being trialled or tested in the Trial and includes any placebo.

**Lead Group:** In an Intergroup trial the 'lead group' is the collaborative group which takes the responsibility for the initiation, management, and/or financing of the Trial. The lead group must have the facilities and resources to be able to fulfil the obligations of this role.

**Monitoring:** The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded and reported in accordance with the protocol, Standard Operating Procedures, Good Clinical Practice, and the applicable regulatory requirement(s)<sup>1</sup>.

**Multi-Centre Trial:** A trial conducted by several investigators according to a single protocol at more than one trial site<sup>1</sup>.

**National Ethics Application Form (NEAF):** A web-based tool that has been developed to enable researchers of all disciplines to complete research ethics proposals for submission to Human Research Ethics Committees (HRECs), and to assist HRECs to consistently and efficiently assess these proposals<sup>13</sup>.

**New Proposal:** A new trial concept, protocol synopsis or full protocol submitted to the TROG Scientific Committee (TSC) for consideration of further development.

**New Technologies and Techniques Committee:** The TROG New Technologies and Techniques Committee (NTTC) was formed with the aim to support the TROG Scientific Committee and Trial Chairs in managing the inclusion of advanced radiotherapy technology and techniques into trials. This involves identifying new technologies and techniques that would be relevant for TROG.

**Objectives:** The general questions the trial was designed to answer. May be associated with one or more hypotheses that, when tested, will help answer the question<sup>10</sup>.

**Open to Accrual:** A trial is considered open to accrual when the first Trial site has submitted all required regulatory and ethical documentation and has been approved for activation by the Trial Coordinating Centre.

**Outcome:** An outcome variable of interest in the trial (also called an end point). Differences between treatment groups in the outcome variable(s) are believed to be the result of the differing interventions. The primary outcome is the outcome of greatest importance. Data on secondary outcomes are used to evaluate additional effects of the intervention<sup>10</sup>.



**Participant:** An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control (receiving standard care). This term can be used interchangeably with 'Trial Patient'.

**Participant Information Sheet and Consent Form (PIC):** The Participant Information Sheet is a detailed written description of all aspects of the trial in accordance with section 4.8.10 of the ICH GCP Guidelines.

**Patient:** Means a person who is receiving medical attention, care or treatment.

**Patient Reported Outcome:** A questionnaire used in a clinical trial or a clinical setting, where the responses are collected directly from the patient.

**Phase I Trials:** The first step in testing a new treatment in humans. These trials test the best method of administration and the best dose<sup>14</sup>.

**Phase II Trial:** A trial to study the safety, dosage levels, efficacy and response to a new treatment<sup>14</sup>

**Phase III Trial:** A trial to compare the results of people receiving a new treatment, with the results of people receiving the standard treatment (for example, which group has better survival rates or fewer side effects). In most cases, studies move into phase III only after a treatment is seen to work in phases I and II trials. Phase III trials may include hundreds of people<sup>14</sup>.

**Phase IV Trials:** After a treatment has been approved and is being marketed, it is studied in a phase IV trial to evaluate side effects that were not apparent in the phase III trial. Thousands of people are involved in a phase IV trial<sup>14</sup>.

**Placebo:** A substance not containing an active agent under study, administered to some trial participants to compare the effects of the active agent administered to other trial participants<sup>15</sup>.

**Principal Investigator (PI):** A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the PI is the responsible leader of the team<sup>1</sup>.

**Primary Data:** Data collected by the Investigator conducting the research.

**Proponent:** The Investigator that prepares and presents a new trial proposal to TROG. The term Proponent is used until the trial has been approved for development. The Proponent is then referred to as the Trial Chairperson.

**Protocol:** A document that describes the objective(s), design, methodology, statistical considerations, and organisation of the Trial. This document may be amended from time to time and must then be approved again by the responsible HREC<sup>1</sup>.

**Protocol Amendment:** A written description of a change(s) to, or formal clarification of a protocol.

**Protocol Deviation:** A failure to adhere to the pre-specified trial protocol, or a participant for whom this occurred. For example participants are found to have been included in the trial by mistake

(they were ineligible) and those for whom the intervention or other procedure differed from that outlined in the protocol<sup>10</sup>.

**Quality Assurance (QA):** All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated; documented (recorded); and reported in compliance with Good Clinical Practice and the applicable regulatory requirement(s)<sup>1</sup>.

**Quality Control:** The operational techniques and activities undertaken within the quality assurance system to verify that requirements for quality of the trial related activities have been fulfilled<sup>1</sup>.

**Quality of Life (QOL):** A broad-ranging concept that incorporates an individual's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationships to salient features of the environment.

**Randomisation:** The process of assigning trial participants to treatment or control groups, using an element of chance to determine the assignment in order to reduce bias<sup>1</sup>.

**Ratification:** The act of the TROG Scientific Committee granting official approval or acceptance to trial related documentation and/or development.

**Recruitment:** Process used by investigators to consent and register eligible participants onto a clinical trial.

**Registration:** The act of assigning a trial participant with a unique trial identification number.

**Regulatory Authorities:** Bodies with the power to regulate. In the ICH GCP guidelines the expression Regulatory Authorities includes the authorities that review submitted clinical data and those that conduct inspections. These bodies are sometimes referred to as competent authorities<sup>1</sup>.

**Research Governance:** Those matters concerning the 'quality, safety, privacy, risk management, financial management and ethical acceptability' of research at a particular institution.

**Research Government Officer (RGO):** A person assigned to the management and oversight of research governance at a particular institution.

**Results:** Means all results and/or data obtained within the framework of the Trial, and specifically in (i) the final report ("Statistical Report") and (ii) the Data Base.

**Risk-Benefit Ratio:** The risk to individual trial participants versus the potential benefits. The risk/benefit ratio may differ depending on the condition being treated<sup>2</sup>.

**Sample size:** The number of participants calculated for a clinical trial, which takes into account potential dropout rates of participants and calculates the number of participants that a change is needed to be observed in, in order to achieve the trial's aims and objectives.

**Satellite Site:** A centre where expert services are provided from a main institution that falls under the governance of that institution or Area Health Service.

**Screening:** The process of evaluating a patient with respect to the eligibility criteria of the trial.

**Secondary Data:** Data collected by someone other than the investigator conducting the research.

**Serious Adverse Event (SAE):** Any adverse event or adverse drug reaction which results in death; is life-threatening; requires inpatient hospitalisation or prolongation of existing hospitalisation; results in persistent or significant disability/incapacity; or is a congenital anomaly/birth defect<sup>1</sup>.

**Side Effects:** Any undesired actions or effects of a drug or treatment. Negative or adverse effects may include headache, nausea, hair loss, skin irritation, or other physical problems. Experimental drugs must be evaluated for both immediate and long-term side effects<sup>2</sup>.

**Single Ethical Review for Multicentre Research:** A system where a lead Human Research Ethics Committee (HREC) is accredited to undertake a single ethical and scientific review of human research to be conducted at multiple centres within participating states in Australia. The purpose of the Single Ethical Review system is to establish a mechanism whereby every research project is ethically and scientifically reviewed once only, with Public Health Organisations accepting the review undertaken by a lead HREC as a sufficient review for the purposes of the project being conducted at institutions under its control<sup>16</sup>.

**Site Trial Coordinator:** The Site Trial Coordinator (STC) is responsible for the day-to-day activities of a clinical trial at a Trial Site.

**Site Specific Assessment (SSA):** A separate form and review process used to determine whether a project has satisfied the research governance requirements of the site.

**Source Data:** All information contained in original records and certified copies of original records such as clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents<sup>1</sup>.

**Source Documents:** Original documents, data and records (e.g. hospital records; clinical and office charts; laboratory notes; memoranda; patient's diaries or evaluation checklists; pharmacy dispensing records; recorded data from automated instruments; copies or transcriptions certified after verification as being accurate copies; microfiches, photographic negatives, microfilm or magnetic media; x-rays; patient files; and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial)<sup>1</sup>.

**Sponsor:** An individual, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial<sup>1</sup>.

**Standing Committee On Therapeutic Trials (SCOTT):** Scientific assessment of clinical trials is undertaken by the SCOTT. SCOTT is a standing committee of the Health Research Council of New Zealand and consists of specialists from a range of health fields.

**Stopping Rule:** A statistical criterion that, when met by the accumulating data, indicates that the trial can or should be stopped early to avoid putting participants at risk unnecessarily or because the intervention effect is so great that further data collection is unnecessary. Usually defined in the trial protocol and implemented during a planned interim analysis<sup>10</sup>.

**Sub Investigator:** Any individual member of the clinical trial team, designated and supervised by the Principal Investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g. associates, residents, research fellows, registrars)<sup>1</sup>.

**Sub-study:** A sub-study is essentially an add-on study to the main protocol, designed to ask a separate research question and which includes new data collection from some or all of the trial participants participating in the main protocol<sup>17</sup>.

**Suspended:** Recruiting or enrolling trial participants to a clinical trial has halted prematurely but potentially will resume.

**Terminated:** Recruiting or enrolling trial participants to a clinical trial has halted prematurely and will not resume; trial participants may or may not be continuing with examinations or treatment.

**Treatment Effect:** A measure of the difference in outcome between intervention groups. Commonly expressed as a risk ratio (relative risk), odds ratio or risk difference for binary outcomes and as difference in means for continuous outcomes. Often referred to as the "effect size"<sup>10</sup>.

**Trial Chairperson:** The Investigator assigned the overall responsibility for the development and coordination of a multicentre clinical trial.

**Trial Coordinating Centre (TCC):** Means the site, facility or clinical research organisation appointed by the Trial Chairperson to carry out trial development, trial initiation, data management procedures including maintenance of the Trial Database, liaison with Trial Sites participating in the trial, randomisation services and statistical analysis.

**Trial Data:** Means the information collected from source data which is recorded on the Case Report Forms and entered into the trial database for future analyses.

**Trial Management Committee (TMC):** A multidisciplinary committee, chaired by the Trial Chairperson, responsible for the overall supervision of a multicentre trial.  
See: 'Trial Executive Committee'.

**Trial Master File (TMF):** A file that contains all of the essential documents relating to a clinical trial, before the trial commences, during trial conduct and after the trial.

**Trial Registration Number:** A unique identifier assigned at the time of registration to each trial participant to protect the participant's identity and used in lieu of the participant's name when adverse event and/or other trial related data are reported<sup>1</sup>.

**Trials Review Meeting:** In each calendar year TROG convenes a Trials Review Meeting where Trial Chairpersons of each trial provide an update on the conduct of their trial.

**Trial Site:** The location(s) where trial-related activities are actually conducted<sup>1</sup>. (Usually within the institution where the Principal Investigator is based)

**Trial Status:** Indicates the current stage of a trial, whether it is a new concept (proposal), in development, activated, or completed. See: New Proposal, Approved for Development, Approved for Activation, Open, Closed, Completed, Suspended, Terminated, Withdrawn.

**TROG Board:** TROG is a company limited by guarantee, managed by an elected Board of directors.

**TROG Central Operations Office (TCOO):** The TROG Central Operations Office is based at the Calvary Mater Newcastle and is responsible for the central coordination of all TROG research activities including quality assurance.

**TROG Affiliate Membership:** Data managers, radiation therapists, medical physicists, statisticians, registrars, medical oncologists, surgeons, nurses and radiologists or professionals involved in another clinical discipline that relates to TROG's clinical trials and accepts the aims of the TROG as set out in TROG's constitution are eligible to become an Affiliate Member. Affiliate Members do not hold voting rights and are not required to pay the annual subscription fee.

**TROG Full Membership:** Open to radiation oncologists who have an interest in research in the practice of radiation oncology, and who accept the aims of TROG. Full Members may vote at meetings of Members and must pay an annual subscription fee.

**TROG Life Membership:** In special circumstances the TROG Board will recommend that an existing member be nominated for life membership and put forward a resolution nominating that person to become a Life Member. Voting members may then pass the resolution awarding the nominee a Life Membership. Life Members may vote at meetings of Members and are not required to pay an annual subscription fee.

**TROG Policy Statements:** A set of established documents that describe TROGs policies.

**TROG President:** The president of the Board of Directors of the Trans Tasman Radiation Oncology Group.

**TROG Publications Committee (TPC):** Provides independent scientific review of manuscripts prior to submission and ensures that the results of TROG trials are reported on in a timely manner.

**TROG Scientific Committee (TSC):** An advisory committee to the Board appointed to oversee the scientific research activities of TROG.

**TROG Number:** A unique number allocated to all TROG trials which signifies that a trial has met the TROG trial development milestones and has been given permission by the TSC to commence site activation processes. The first two numbers identify the year of approval and the last two identify the sequential allocation of approval in that year. For example, the third trial approved in 2008 would be allocated the number 08.03.

**Withdrawn:** Trial halted prematurely, prior to enrolment of first trial participant.

## ABBREVIATIONS

ADR	Adverse Drug Reaction
AE	Adverse Event
AGM	Annual General Meeting
ANZCTR	Australian New Zealand Clinical Trials Registry
ANC	Absolute Neutrophil Count
AUC	Area Under the Curve
ASM	Annual Scientific Meeting
BaCT	Centre for Biostatistics and Clinical Trials
BSA	Body Surface Area
CRF	Case Report Forms
CRT	Conformal Radiotherapy
CT	Computerised Tomography
CTA	Clinical Trial Agreement
CTC AE	Common Terminology Criteria for Adverse Events
CTN	Clinical Trial Notification
CTX	Clinical Trial Exemption
CTV	Clinical Target Volume
DQLI	Dermatology Quality of Life Index
DRR	Digitally Reconstructed Radiographs
DVH	Dose Volume Histogram
ECOG	Eastern Co-operative Oncology Group
EGFR	Epidermal Growth Factor Receptor
FACIT	Functional Assessment of Chronic Illness Therapy
FACT	Functional Assessment of Cancer Therapy
FBE	Full Blood Examination
FDG-PET	FluoroDeoxyGlucose – Positron Emission Tomography
FDG-PET-CT	FDG-PET Computed Tomography
FFS	Failure-Free Survival
FNA	Fine Needle Aspirate
GCP	Good Clinical Practice
GTV	Gross Tumour Volume

Hgb	Haemoglobin
HHIA-S	Hearing Handicap Inventory for Adults - Screening version
HPV	Human Papilloma Virus
HREC	Human Research Ethics Committee
HRQOL	Health-Related Quality Of Life
ICH	International Conference on Harmonisation
IB	Investigator's Brochure
IDSMC	Independent Safety Data Monitoring Committee
IHC	ImmunoHistoChemistry
IRB	Independent Review Board
LRF	LocoRegional Failure
LTF	Liver Function Test
MDASI-HN	M.D. Anderson Symptom Inventory – Head and Neck
MID	Minimal Important Difference
MRI	Magnetic Resonance Imaging
NCI	National Cancer Institute
NEAF	National Ethics Application Form
OAR	Organ At Risk
OPC	OroPharyngeal Cancer
OPSCC	OroPharyngeal Squamous Cell Carcinoma
OS	Overall Survival
PEG	Percutaneous EnteroGastric
PIC	Patient Information sheet and Consent form
Plt	Platelets
PRO	Patient Reported Outcome
PRV	Planning organ at Risk Volume
PSS	Performance Status Scale
PTV	Planning Tumour Volumes
QA	Quality Assurance
QALY	Quality-Adjusted Life Year
RT	Radiation Therapy

RTP	Radiotherapy Treatment Planning
SAE	Serious Adverse Event
SCC	Squamous Cell Carcinoma
SCOTT	Standing Committee On Therapeutic Trials
TCC	Trial Coordinating Centre
TGA	Therapeutic Goods Administration
TMC	Trial Management Committee
TSC	TROG Scientific Committee
TMF	Trial Master File
TCOO	TROG Central Operations Office
TPC	TROG Publications Committee
UAE	Unexpected Adverse Events
3D	3-Dimensional



## COLLABORATING GROUP ACRONYMS

AGITG	Australasian Gastro-Intestinal Trials Group
ALLG	Australasian Leukaemia & Lymphoma Group
ANZBCTG	Australian/New Zealand Breast Cancer Trial Group
ANZGOG	Australia New Zealand Gynaecological Oncology Group
ANZLG	Australian and New Zealand Lymphoma Group
ANZMTG	Australia and New Zealand Melanoma Trials Group
ANZUP	Australian and New Zealand Urogenital and Prostate Cancer Trials Group
AROLG	Australasian Radiation Oncology Lymphoma Group
CSSANZ	Colorectal Surgical Society of Australia and New Zealand
EORTC	European Organisation for Research and Treatment of Cancer
MaNGO	Mario Negri Gynecologic Oncology group
MRC UK	Medical Research Council, United Kingdom
NCCTG	North Central Cancer Treatment Group
NCIC CTG	National Cancer Institute of Canada Clinical Trials Group
NCRI	National Cancer Research Institute
NSABP	National Surgical Adjuvant Breast and Bowel Project
OCOG	Ontario Clinical Oncology Group
PoCoG	Psycho-oncology Co-operative research Group
RANZCR	Royal Australian and New Zealand College of Radiologists
RTOG	Radiation Therapy Oncology Group
SWOG	South West Oncology Group
USANZ	Urological Society of Australia and New Zealand
VCOG	Victorian Cooperative Oncology Group

## REFERENCES

1. Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with TGA comments (DSEB July 2000).
2. Clinical Trials.gov [homepage on the Internet]. Maryland: A service of the U.S. national Institute of Health; [updated 2007 April 17; cited 2008 July 17]. Available from: <http://clinicaltrials.gov/ct2/info/glossary>
3. Queensland Clinical Trials Network Inc. [homepage on the Internet]. Queensland: QCTN; c2007 [cited 2008 July 17]. Glossary [about 2 screens]. Available from: <http://www.qctn.com.au/publicinfo/Glossaryofterms/tabid/183/Default.aspx>
4. Australian Government, Department of Health and Aging, Therapeutic Goods Administration [homepage on the Internet]. ACT: The TGA [update 2007 Dec 17; cited 2008 July 17]. Clinical trials at a glance; [about 1 screen]. Available from: <http://www.tga.gov.au/ct/ctglance.htm>
5. Australian Government, Department of Health and Aging, Therapeutic Goods Administration. Access to unapproved therapeutic goods - Clinical trials in Australia, October 2004.
6. Watson, Richard T. *Data Management*. Hoboken, NJ: Wiley, 2000
7. Guideline on Data Monitoring Committees. European Medicines Agency. EMEA/CHMP/EWP/5872/03 Corr. 27 July 2005. (Adopted by TGA January 2006)  
Available at: <http://www.tga.gov.au/docs/pdf/euguide/ewp/587203final.pdf>
8. NSW Health. Standard Procedures for Working with Health Care Interpreters. Policy Directive PD2006\_053. 2006 July 11.
9. Eastern Cooperative Oncology Group [homepage on the Internet]. Brussels: EORTC; c1998-01 [updated 2006 July 27; cited 2008 July 17] ECOG Performance Status (one screen). Available from: <http://ecog.dfci.harvard.edu/>
10. Altman DG, Schulz KF, Moher D, Egger M, Davidoff F, Elbourne D, Gøtzsche PC, Lang T. The revised CONSORT statement for reporting randomised trials: explanation and elaboration. *Ann Intern Med* 2001; 134(8):663-694.
11. ICH GSEM [homepage on the Internet]. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use [cited 2008 July 17]. Available from: <http://www.ich.org/cache/compo/276-254-1.html>
12. A Manual for Participants in Clinical Trials of Investigational Agents Sponsored by DCTD, NCI (2002)
13. National Ethics Application Form [homepage on the Internet]. Commonwealth of Australia: c2004 [updated unknown; cited 2009 August 21]. Available from: <https://www.neaf.gov.au/Default.aspx>
14. National Cancer institute [homepage on the Internet]. Maryland: Dictionary of Cancer Terms; [cited 2008 July 17]. Available from: <http://cip.cancer.gov/dictionary/?expand=P>
15. National Statement on Ethical Conduct in Human Research, (Australia, 2007).
16. New South Wales Government Department of Health [homepage on the Internet]. Policy Directive 'Research - Model for Single Ethical & Scientific Review of Multi-Centre Research'. Available at: [http://www.health.nsw.gov.au/policies/pd/2007/pdf/PD2007\\_072.pdf](http://www.health.nsw.gov.au/policies/pd/2007/pdf/PD2007_072.pdf)
17. Meinert CL, editor. Sub-study, ancillary study, and auxiliary study good practice policies and procedures [memo on the Internet]. Maryland: Johns Hopkins University, Centre for Clinical Trials; [cited 2008 July 17]. Available from: <http://www.jhucct.com/clm/gppps/Ann.pdf>