

Clinical Trials Advisory and Awards Committee (CTAAC)

Terms of Reference, Updated July 2007

1. Remit

- 1.1. On behalf of Cancer Research UK, to review and fund as CTAAC, cancer clinical trials (mainly phase III therapeutic and some large phase II clinical trials). In addition, to peer review proposals for company funded (University/Trust sponsored) phase III clinical trials. Both of these to result in a national portfolio of high quality phase III trials.
- 1.2. In fulfilment of this, CTAAC will work with:
 - Cancer Research UK's Clinical and Translational Research Committee (CTRC) and where appropriate other Funding Committees, to ensure co-ordination of activities and appropriate input to the development of strategies and policies.
 - Appropriate Committees or panels such as Medical Research Council, HTA and LRF
 - The NCRI and NCRN, including the site specific and cross-cutting NCRI Clinical Studies Groups.

2. Terms of Reference

- 2.1. To manage a defined budget, to be set by the SEB, for response mode funding of phase III trials.
- 2.2. Trials costing a total of more than £1 million will be reviewed and scored by CTAAC and its decision will be ratified by CTRC.
- 2.3. To review, prioritise and fund phase III clinical trials (and some large phase II clinical trials) via defined funding mechanisms.
- 2.4. To review outline and full applications, on behalf of CR UK for all phase III clinical trials, including some primary prevention trials involving medical interventions (e.g. chemoprevention or vaccines) and some secondary prevention trials (e.g. use of aspirin in patients with colorectal polyps).
- 2.5. To ensure the maintenance of an internationally competitive research portfolio, which is targeted to the fulfilment of Cancer Research UK's mission and goals, by allocating resources on the basis of scientific excellence, likely impact on policy and practice and relevance to Cancer Research UK's scientific strategy.
- 2.6. To apply peer review of the highest international standards and to engage the appropriate additional expertise in the assessment of applications.
- 2.7. To ensure written confirmation of the 'Sponsor' for the trial, as required under the EU Clinical Trials Directive (2001/20/EC-[EUCTD]), and or the Department of Health Research Governance, before funding/endorsement is provided.

- 2.8. To ensure that all trials are conducted to the highest ethical standards with due consideration to issues of informed consent, data protection and confidentiality and where appropriate the provision of any insurances.
- 2.9. To monitor the progress of trials funded by CTAAC and ensure that appropriate steps are taken in order that trials meet agreed standards and complete and report in a timely manner.
- 2.10. To monitor the results and outcomes of trials funded by CTAAC and to report these outcomes at least annually to CTRC/SEB.
- 2.11. To keep abreast of, and where relevant address, external factors such as government policies, which impact on Cancer Research UK's CTAAC portfolio.
- 2.12. To identify and bring to the attention of the SEB opportunities for partnerships and collaborations, including joint funding and/or implementation initiatives, and to develop special calls for proposals in priority areas where appropriate.
- 2.13. To liaise with the Translational Research in Clinical Trials Committee (TRICC) with regards to funding for applications for funding of sample collections and translational research associated with clinical trials and provide advice on the potential utility of sample collections.
- 2.14. To receive Executive Summaries of the funding decisions of TRICC and the Feasibility Study Committee (FSC).
- 2.15. To provide Executive Summaries and feedback letters to the relevant Funding Committees.

3. Membership

- 3.1. The membership will be:
 - The Chairman of CTAAC will be independent from CR UK and a non-oncologist, who will also serve as a member of CTRC.
 - There will be two Vice-Chairs, both of whom will be oncologists and have complementary expertise.
 - Members will be drawn from clinicians, statisticians and Professions Allied to Medicine with appropriate expertise relevant to the portfolio. There will be two independent and/or lay members. An NRCN observer will also be invited.
 - An international panel of experts will review outline applications.
- 3.2. No more than 2/3 of members will be in receipt of response-mode Cancer Research UK funding; and less than half of the members should be in receipt of grants from CTAAC.
- 3.3. No more than two members should be from the same institution (without prior endorsement from SEB).
- 3.4. Members will be appointed for an initial term of three years renewable for a further period of up to three years. After a three-year period consideration may be given to a member's re-appointment to CTAAC.

- 3.5. Members of CTAAC may also serve as members of up to one other Cancer Research UK Funding Committee.

4. Meetings

- 4.1. The Committee will meet three times a year. The need and frequency of meetings will be kept under review.
- 4.2. The minutes or executive summary of each meeting will be presented to the Clinical and Translational Research Committee and via that Committee to the Scientific Executive Board.
- 4.3. The Committee will operate mechanisms for recording members' interests and for dealing with potential conflicts of interests during the conduct of its business.

5. Reviews

- 5.1. These Terms of Reference will be reviewed in July 2008.