Radiotherapy Clinical Trials Advisory Service (RADCAS)

The National Cancer Research Institute (NCRI) Clinical and Translational Radiotherapy Research Working Group (CTRad) actively supports the development of radiotherapy research proposals. Proposals reviewing meetings are organised up to twice a year for researchers to submit trial ideas for open and interactive discussion with experts, who will give comments and help push the proposals to the next stage. To supplement the time in between reviewing meetings, a Radiotherapy Clinical Trials Advisory Service, or RADCAS, is available at any time of the year, offers the opportunity for researchers to obtain expert advice from CTRad members.

Aim

To offer specialist radiotherapy trials advise to Investigators, and trial funding bodies, including trial methodology, radiotherapy technical expertise, and translational research opportunities. This service is available at any time of the year, and supplements the opportunities for researchers to present and engage in interactive discussion at the twice-yearly All-Workstreams meetings.

Background

CTRad Workstream 3 has developed a process by which all new clinical trial proposals to the NCRI have access to a 'Radiotherapy Clinical Trials Advisory Service' (RADCAS). This offers potential investigators an advice service for any trial in which radiotherapy is a significant component. Clinical Trials methodology advice will be available through the MRC Hubs for Trials Methodology Research. Tumour site specific advice and advice on translational research components will be provided by members of WS3.

Checklist for components of a radiotherapy trial

An important step towards delivering good quality radiotherapy within a clinical trial is developing a radiotherapy protocol. Here is a summary:

1. The clinical trial should have a named radiotherapy investigator responsible for the radiotherapy components of the trial.
2. A detailed Radiotherapy target volume definition protocol should be produced to guide local radiotherapy investigators.
3. Protocols for Radiotherapy planning and delivery technique should be produced, including all aspects of required quality assurance.
4. Consideration should be given to developing aspects of trial methodology which could allow testing of radiotherapy research questions
5. Translational studies such as biomarker investigation or tissue sample collection and storage should be considered.

CTRad Workstream 3 has developed a checklist of key components of such protocols for investigators to ensure nothing is omitted when they develop their trial protocol. This checklist can be downloaded from the CTRad website.

Referrals to RADCAS should ideally be made from tumour site specific CSGs during the trial design stage, thus allowing time and opportunity for the above considerations.

Trials with a significant radiotherapy component will be referred by CTAAC at outline or full application stage.

At the time of referral, the trial would be reviewed by the Co-chairs of WS3, and specialist reviewers would be allocated. This might be based on tumour site, radiation technique, methodology, or other aspects.

The review would be anticipated to be rapid and add value to the project. The CTRad Secretariat (Carolyn Chan) would collate written feedback which would be given to the referrer (either CTAAC or the Investigator). If RADCAS was engaged at the trial design phase, then more detailed interaction with the trial investigator may be appropriate in the form of teleconference or informal face to face meeting.

The Chief Investigator of the proposal could be invited to present their trial at the next CTRad All-Workstreams and proposals reviewing meeting (up to twice a year), meeting of the WS3 (for phase 3 trials) or WS2 (for phase 1/2 trials) to gain the group's feedback.

Resources and contact for advice for RADCAS process

1. Initial approach.
   Trial Principal Investigators are encouraged to approach the co-chairs of Workstream 3 in the first instance either directly or via the CTRad Secretariat (Carolyn Chan).
   Contact:
   Chris Nutting (Chris.Nutting@rmh.nhs.uk)
   Emma Hall (Emma.Hall@icr.ac.uk)
   Carolyn Chan (Carolyn.chan@ncri.org.uk)

2. Methodology, health economics and quality of life
   The MRC Hubs for Trials Methodology Research can be contacted via administrator of the Hub, Dr Emily Crowe.
   Contact: Emily Crowe (emc@ctu.mrc.ac.uk)

3. Translational research, biomarkers and imaging
   Contacts for translational research questions for radiotherapy trials should be directed to Professor Catharine West and Dr Don Jones.
   Contact:
   Catharine West (catharine.west@manchester.ac.uk)
   Don Jones (gdj2@leicester.ac.uk)

4. Radiotherapy protocol development, QA and technical enquiries should be directed to the National Radiotherapy Trials Quality Assurance Team (RTTQA) coordinator.
   Contact: Elizabeth Miles (elizabeth.miles@nhs.net)

Notes

RADCAS may be relevant for early phase trials as well as phase III trials.

RADCAS would only review currently open trials if requested. The purpose of this would be to assist with issues listed above if the protocol was felt to be deficient in important areas relevant to the Workstreams.

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