

RTOG Modality Review Guidelines

RT quality reviews:

- Full review for phase I and phase II trials.
- There will be a full review for phase III trials with a radiation treatment question or where the radiation treatment is novel and/or non-standard.
- Studies in which the primary endpoint is an efficacy endpoint other than overall survival (e.g., response rate, disease free survival, relapse free survival, local control, etc.) will have a full review of the diagnostic imaging (CT and/or MRI and/or PET). An appropriate study chair (neuro-radiologist, diagnostic radiologist) will be identified before study activation.
- The radiation oncologist study chair, the study dosimetrist, the study senior statistician, and the disease site chair will evaluate other Phase III trials that deliver standard radiation treatment and if possible, the RT quality reviews will be by sampling. The radiation oncologist study chair of the trial, the senior statistician, and the supporting data manager will collaboratively decide on the type of RT review for each trial.
- There may be selected studies with a radiation treatment question that do not need a full review, for example, RTOG 0214, which investigates the effects of prophylactic cranial irradiation on survival for NSCLC patients with good response to definitive treatment.
- To prepare for an RT review, the radiation oncology study chair will:
 - (1) carefully review the study rationale and objectives for RT delivery,
 - (2) review the primary objectives of the study,
 - (3) review RT scoring criteria for field borders, dose, fractionation, and elapsed days,
 - (4) know the eligibility criteria, and
 - (5) delineate reasons for treatment discontinuation and protocol treatment discontinuation.

Chemotherapy/biologic reviews:

- Full review for Phase I trials.
- Full review for IND trials.
- Full review for Phase II trials with a chemotherapy efficacy question, and Phase III trials that compare chemotherapy regimens (as opposed to comparing RT regimens). The disease site medical oncology chair, the medical oncologist study chair of the trial, the senior statistician, and the supporting data manager, will collaboratively decide on the type of chemotherapy/biologic review for a trial.
- To prepare for a chemotherapy/biologic review, the medical oncology study chair will:
 - (1) carefully review the study rationale and objectives,
 - (2) review the primary objectives of the study,
 - (3) establish appropriate dosing and schedule and dose modifications from the protocol instructions,
 - (4) know the eligibility criteria,
 - (5) understand standard follow-up parameters and scheduling, and
 - (6) delineate reasons for treatment discontinuation and protocol treatment discontinuation.

Chemotherapy/biologic reviews of studies other than those described above will be by sampling.

Surgical reviews:

Surgical quality control is an important part of clinical trials involving surgical treatment.

Surgical reviews, largely using operative notes and pathology reports, have been the mainstay of surgical quality control within the RTOG. There are essentially four types of trials involving surgery:

- In trials where surgery, and/or the surgical specimen, are important components of eligibility criteria prior to patient registration, but not part of the trial itself, a modified surgical review of pathology and operative reports for these trials will be performed on all patients. In these trials, no S-1 form is developed because surgery is not part of the trial, however, quality control of eligibility is important.
- For trials in which surgical therapy is applied to only a portion of the trial population (“surgical salvage”), the protocol will be reviewed during development by a member of the RTOG Surgical QC Committee who will decide in conjunction with the protocol surgical study chair and the RTOG Surgical QC Committee Chair regarding the need, and type surgical review. Data collection for such a review, when required, could include OR and pathology notes, radiation therapy reports, and chemotherapy reports, but the specific data to be collected for surgical salvage reviews will be specific and unique to each protocol. Surgical salvage reviews will not be done by sampling; data on all patients will be reviewed. Trials that include surgical salvage reviews can also have surgical reviews of patients who receive surgery.
- Trials in which surgery is part of the treatment schema, but not the central research question of the trial require a full surgical review of all patients.
- In trials with one or more research hypotheses involving surgical procedures specified in the trial, surgical quality control is essential. Such trials will have input from the Surgical Quality Control Committee during the protocol development phase to ensure that the appropriate surgical review is planned and quality control mechanisms are optimal. A full surgical review of all patients is necessary for these studies.
- To prepare for a surgical review the study chair(s) will:
 - (1) carefully review the study rationale and objectives,
 - (2) review the primary objectives,
 - (3) establish appropriate criteria for evaluation of per protocol, deviation, etc.,
 - (4) know the eligibility criteria,
 - (5) understand standard follow-up parameters and scheduling, and
 - (6) ensure that appropriate source documents (OR, pathology reports) have been collected for the review.

Hormone Reviews:

- Full review for phase I/II studies
- Phase III studies will be evaluated by the radiation oncologist study chair, the medical oncology and urology study chair (if applicable), the study senior statistician, and the disease site chair. If possible, the hormone delivery quality reviews will be by sampling. Phase III studies with a hormone therapy question, or in which the hormone therapy is novel and/or non-standard, will not generally be sampled for hormone therapy quality reviews. Since the radiation oncology study chair has responsibility for both RT and hormone delivery quality reviews, this workload should be considered and distributed appropriately between study chairs.
- To prepare for a hormone therapy review, the radiation oncology study chair will:
 - (1) carefully review the study rationale and objectives,
 - (2) review the primary objectives of the study,
 - (3) establish appropriate RT and treatment breaks from the protocol instructions,
 - (4) know the eligibility criteria,
 - (5) understand standard follow-up parameters and scheduling, and
 - (6) delineate reasons for treatment discontinuation and protocol treatment discontinuation.

Supportive Care Reviews:

- Supportive care studies are typically CCOP studies and may involve agents for which review criteria do not exist. If so, the CCOP and medical oncology study chairs will have to specify appropriate review criteria as part of the protocol development.
- Full review for phase I and phase II trials.
- Full review for Phase III trials in which the question at hand compares supportive care regimens. Full review mandates sign off by the study chair of the trial.
- To prepare for a supportive care review the study chair(s) will:
 - (1) carefully review the study rationale and objectives,
 - (2) review the primary objectives,
 - (3) establish appropriate dosing and dose modifications from the protocol instructions,
 - (4) know the eligibility criteria,
 - (5) understand standard follow-up parameters and scheduling, and
 - (6) delineate reasons for treatment discontinuation and protocol treatment discontinuation.

Supportive care reviews of studies other than those described above will be by sampling.

Complementary Therapy Reviews:

- Complementary therapy studies are typically CCOP studies and usually involve agents for which review criteria do not exist. If so, the CCOP study chair, with other study chairs as appropriate, will have to specify appropriate review criteria as part of the protocol development.
- Full review for phase I and phase II trials.
- Full review for Phase III trials in which the question at hand compares complementary therapy regimens. Full review mandates sign off by the study chair of the trial.
- To prepare for a complementary therapy review the study chair(s) will:
 - (1) carefully review the study rationale and objectives,
 - (2) review the primary objectives,
 - (3) establish appropriate dosing and dose modifications from the protocol instructions,
 - (4) know the eligibility criteria,
 - (5) understand standard FOLLOW-UP parameters and scheduling, and
 - (6) delineate reasons for treatment discontinuation and protocol treatment discontinuation.

Supportive care reviews of studies other than those described above will be by sampling.