

AbstractID: 14288 Title: QARC QA of Imaging and Radiation Therapy Improves Protocol Compliance in Advanced Technology Cancer Clinical Trials

**Purpose:** To describe the imaging management, radiation therapy quality assurance, and central review services that the Quality Assurance Review Center (QARC) provides for NCI sponsored adult and pediatric multi-institutional clinical trials.

**Method and Materials:** QARC has an in-house developed, validated database that houses data on protocol patients for COG, ACOSOG, CALGB, PBTC, SWOG and ECOG. Diagnostic CT, MR, and PET imaging studies are linked to patient protocol data and available for review concurrent with radiation therapy treatment plans and data and with response imaging. Tools allow remote, web-based review by study investigators as well as QARC staff to assess protocol compliance.

**Results:** The QARC archive includes protocol data on >49,000 patients and >51,000 diagnostic imaging studies. Central review at QARC of imaging and radiation treatment plans increases protocol compliance. For example, 5 year relapse free survival in Hodgkin protocol POG 8725 was 86% for patients with deviations in the treatment volume and 96% for patients with appropriate volumes as assessed at QARC central review. In a head and neck trial in which central review was performed, survival at 2 years was >70% for patients whose target volumes and dose were protocol compliant; it was 50% for those non-compliant. These outcomes have resulted in many protocols requiring pre-treatment central review.

**Conclusion:** Central review of imaging and radiation treatment plans and data are essential for modern clinical trials which are increasingly complex and image-based. All imaging requires interpretation and consistent interpretation is vital for valid trial outcomes. Radiation therapy treatments require central review to assure target volume definition and dose distributions are protocol compliant. QARC has the database, the tools, and the experienced staff and processes to provide these services efficiently.

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