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Quality Assurance for Clinical Trials: A Primer for Physicists

A report of the Subcommittee on Quality Assurance Physics for Cooperative Trials
of the Radiation Therapy Committee

(An AAPM Report is currently in preparation)

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1) **Introduction**

Today, nearly 70% of all radiation therapy centers participate to some degree in cooperative group (organized, multi-institutional, National Cancer Institute-funded) clinical trials. About 25% of these centers participate actively in that they treat more than 12 patients per year under protocol. In all cases, specific quality assurance procedures need to be performed by the physicist to either be eligible for membership in the cooperative group or to maintain eligibility. In protocols involving radiation therapy, there are radiotherapy quality assurance and data submission requirements for each patient entered into the trial. In addition, participation in advanced technology protocols, 3D conformal, IMRT, stereotactic radiotherapy, or brachytherapy require a significant physics effort to qualify the institution to enter patients and to provide the required data submission for each patient treated under protocol.

In the near future, both the number of centers participating in clinical trials as well as the number of patients enrolled in studies may rise substantially because of the emergence of the National Cancer Institute (NCI) sponsored Cancer Trials Support Unit (CTSU). The CTSU permits patients to be treated under selected protocols by any radiation therapy center meeting the CTSU requirements regardless of whether that center is a member of the cooperative group conducting the study. Thus, physicists who are either rarely or never asked to provide protocol support may soon be routinely involved with the quality assurance and data submission tasks for protocol patients.

In addition to the increased volume of protocol cases with which physicists may be faced, the complexity of radiation therapy protocols and their quality assurance is increasing as 3D conformal and IMRT based studies are being opened. Here the challenge to the physicist is to successfully perform the benchmark tests for institutional certification and then to ensure protocol compliance and provide the various patient-specific data items required by the quality assurance centers. Most physicists today are generally unaware of the demands of these new protocols.
Radiation therapy physics training rarely includes education in clinical trials in general, radiation therapy sections of clinical trials in particular, nor any specific instruction on quality assurance physics procedures necessary for clinical trial participation. This information and the required skills are largely learned on the job. At many institutions where relatively few patients are entered on clinical trials, non-physics personnel may fill out and submit quality assurance data forms, so that the physicist never sees the protocol and its requirements. Where the physicist is asked to prepare and submit data for patients on or completing protocol treatments or to perform measurements and benchmarks for new protocols, the extra work required in this unfamiliar area may be seen as burdensome.

Due to the mission of organizations like the Quality Assurance Review Center (QARC) and the Radiological Physics Center (RPC), institutions participating in clinical trials must demonstrate their ability to meet quality standards on an ongoing basis. It is the responsibility of the physicist at each participating institution to competently perform the measurements and supply the data that these organizations require.

The consistency and accuracy with which each institution delivers radiation treatments are critical in establishing the statistical significance of the findings of the clinical trial. The various quality assurance centers and clinical trial groups have systematized the quality assurance (QA) process to help institutions follow the protocol guidelines so that the treatment dose and volume are per protocol. It is the duty of the knowledgeable institutional physicist to ensure quality treatments and adherence to protocol guidelines that ultimately enhance the ability of the trials to answer the questions posed.

The Subcommittee on Quality Assurance for Clinical Trials of the AAPM Radiation Therapy Committee has undertaken the writing of this primer in order to provide the information and references required for any physicist to be an informed, competent participant and a key resource to each institution involved in cooperative group clinical trials employing radiation therapy. This primer explains:
a) what constitutes a clinical trial,
b) the role of the physicist in preparing and maintaining the institution’s credentials for participating in clinical trials requiring radiation therapy,
c) the special or additional physics tasks are required, both to become credentialed and to meet specific protocol quality assurance and data submission requirements,
d) the quality assurance review process and how is the submitted data evaluated,

and in the Appendices, which are an important adjunct to this document,
e) the three phases of clinical trials,
f) how QA affects the statistical analysis of clinical trials,
g) the data review and resource centers that receive data submissions and what do they do,
h) how to find the various groups involved in conducting and monitoring clinical trials.

The result should be that the physics community, by having a better understanding of the clinical trial quality assurance process, will feel less frustration and more motivation with their important role in determining the most effective treatment strategy for a particular disease.

This presentation will walk through the Primer document followed by a question and answer session.
REFERENCES


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