AbstractID: 4908 Title: Digital data integrity QA for multi-institutional clinical trials

Purpose: The Image-guided Therapy QA Center (ITC) as part of the NCI-sponsored Advanced Technology QA Consortium (ATC) has nearly 15 years experience in performing data integrity QA review for multi-institutional advanced technology clinical trials that require digital data submission. This presentation will report on that experience.

Method and Materials: Participants in some advanced technology multi-institutional clinical trials must be able to submit imaging data as well as RT objects (CT, RT Structure Set, RT Dose, and RT Plan) to the ITC for protocol compliance QA review of contoured volumes and dose coverage/heterogeneity. Data are sent via FTP or on media. However, prior to that QA review, experienced personnel at the ITC carefully review each digital data set in regard to completeness of protocol required elements, format of data, and possible data corruption.

Results: Thus far over 3000 data sets have been submitted to ITC. Unfortunately, data often need resubmission due to problems discovered by ITC. Errors in submission can be divided into five categories: 1) misuse of UI of treatment planning system (TPS), 2) misunderstanding of protocol requirements, 3) non-uniformity of DICOM export implementations by TPS vendors, 4) user error with digital data transfer software, and 5) updated TPS software, whose data export feature no longer is ATC compliant. Statistics of number of resubmissions required as well as specific details of these problems will be presented.

Conclusion: Digital data submission of complete 3D data set is essential for QA of advanced technology clinical trials. However, collection of these data requires review and troubleshooting by experienced personnel to ensure subsequent protocol compliance QA and later still, quality data analysis. A significant portion of the ITC workload involves digital data integrity QA to ensure quality of submitted digital data