

AbstractID: 8471 Title: Update on Digital Data Integrity Quality Assurance for Multi-Institutional Advanced Technology Clinical Trials

Purpose: Report on that part of the cooperative group clinical trial quality assurance (QA) review process referred to as *Digital Data Integrity QA (DDIQA)*.

Method and Materials: Participants in advanced technology clinical trials supported by the Image-guided Therapy QA Center (ITC) must be able to submit 3D digital datasets (images, contours, and dose distributions) to the ITC. Protocol QA review responsibility has been divided between ITC (DDIQA review) and the cooperative group (CG) for *Protocol Compliance QA Review (PCQA)*. DDIQA consists of review of the completeness of protocol required elements, format, spatial registration, and data corruption. For consistency, structures are renamed and dose volume histograms are recalculated. Data are posted to the web-based *Remote Review Tool (RRT)* a component of the ITC's clinical trial QA system (called QuASA²R) for PCQA review, which includes compliance review of target volume and organ at risk contours as well as review of dose compliance by CG reviewers.

Results: ITC has over 13 years experience in receiving/processing over 6000 digital datasets submitted by institutions participating in advanced technology clinical trials. DDIQA metrics show that approximately 30 % of submissions are problematic. Problems can be divided into three categories: (1) misunderstanding of protocol requirements, (2) misuse of treatment planning system (TPS) data export feature, and (3) updated TPS software whose data export feature is no longer compliant with QuASA²R requirements. The time and effort required to perform DDIQA and prepare a case for PCQA varies, depending on protocol complexity.

Conclusion: DDIQA has proven to be essential for QA of advanced technology clinical trials. Thus, total automation of data submission for rapid QA review of clinical trial datasets is not realistic at this time. Work is currently focused on developing tools that help ITC personnel perform DDIQA more efficiently.

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