Abstract

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 reviewers must be able to download data from DICOM (DDIQA) to a workstation-based review environment. This paper describes the procedures and tools developed by the ITC to facilitate the submission, processing, and review of digital data from the principal investigators (PIs) for the purpose of completing the QA review process.

Results: The Image Guided Therapy Quality Assurance (QA) Center (ITC) has been accepting, processing and reviewing digital data submissions for support QA and analysis of advanced technology protocols for the past 14 years. For the past 3 years the ITC has been a part of the NIH-funded Advanced Technology Consortium (ATC) which consists of four collaborative groups and QA centers. Over 7000 case data sets have been submitted by the PIs to the ITC. The PIs are required to submit the complete 3D treatment planning data set from their treatment planning systems. Many of the commercial treatment planning systems are currently capable of implementing digital data export in a standardized format (either DICOM or RTDGa), but the review of the data can be handled by the ITC and made available to the reviewers via a web-based Remote Review Tool (RRT) that allows the reviewer to access the dose distribution and review the plan in terms familiar to the institution and compare these to protocol guidelines. This Protocol Compliance QA and analysis requires Digital Data Integrity QA of the data to occur at the ITC for completeness and integrity of data review. Often data does not come to the ITC in a reviewable form, and the ITC personnel must intervene and investigate issues that need resolution before the data can be processed and reviewed. Thus, at present, the submission and review of digital data is not yet a completely automated process and requires human intervention to make possible a review of a large number of the cases that are submitted to the ITC. The QA tools and processes developed by the ITC have made practical the processing of large numbers of protocol data for review and analysis. Nevertheless, the receipt of reviewable digital data is a critical step in the process that requires relevant information from the submitting institution. In addition to inspecting the reviewable data the ITC also prepares the data for review by renaming structures, combining individual contour sets, and deleting non-anatomical/non-protocol structures so that the PI reviewer only needs to review the protocol required structures. Also, DTVs are recalculated such that a database of dose volume statistics with standard structure names exists for QA analysis and analysis of large numbers of cases.

Methods and Materials

This ITC has been receiving digital data for advanced technology protocols for 14 years using Digital Data Integrity QA (DDIQA) system. Figure 1 shows a flow diagram which illustrates the path of the data from submission to review. Data are converted by the institution’s treatment planning system to either DICOM or RTDGa data exchange files which are then sent to the ITC via SecureFTP or Medic. The ITC receives the digital data at the time of receipt to ensure that it is complete and ready to be processed so that it can be reviewed by the sponsoring group. Another critical step of the ATC’s RRT is the digital data integrity review. Using a proprietary file format based on the DICOM file format, the ITC is able to perform the integrity review. Each data submission is converted to the ITC’s proprietary file format using tools developed by the ITC. Included in this process is the renaming of structures (Figure 3) to a standard naming convention that allows the re-calibration of DVHs and the later analysis of volume statistics among subjects treated on a clinical trial. A significant portion of the data submissions are incomplete or cannot be processed or reviewed for a number of reasons. These problems require human intervention. A request for resubmission of the data or to resolve issues with the data before it can be made available for review. In the coming years these issues are expected to increase and the ITC is prepared to handle this increase.

Conclusions

This work is supported by the National Institutes of Health (NIH) grants 1P01CA100634 and P50CA58117 and J. H. Starkschall and members of the Image-Guided Therapy QA Center (ITC) at Washington University School of Medicine.

References

1. Straube W, Bosch W, Ekcher A, Haynes J, Matthews J, and James P; Washington University School of Medicine, St. Louis, MO and UC Davis School of Medicine, Sacramento, CA; Supported by NICI Grant U24 CA 61847.

Discussion

The most common source of problems in digital data submissions are the following:

• Errors in the use of digital data submission software on the treatment planning device.
• Errors in the understanding of the required protocol elements.
• Errors in the use of FTP and SFTP software.
• Errors in the ATC compliant DICOM export of the treatment planning system.

Conclusions

• The processing of digital data for the review of advanced technology clinical trials is currently only semi-automated, and not yet a totally automated process.
• A focused review of the data collected over the past 2 years shows that approximately 25% of the protocol case data and 25% of phantom data submitted requires human intervention in order to obtain complete, reviewable digital data (Table 1 and Table 2).
• Procedures and tools developed by the ITC have made possible the collection of a large volume of data for these studies. The processing of these data for Protocol compliance QA (Figures 2 and 3), and the creation of a large archive of treatment planning data for these cases for later data mining.

Problems

Over the years several issues have been consistently reported. The following are examples of these issues:

1. Misuse of Treatment planning system data export capabilities.
2. Missing protocol required elements or mistakes in protocol understanding.
3. Error in use of digital transfer software.
4. New release of treatment planning system with inability to correctly submit ATC data.
5. Problems in categories 1, 2, and 3 are seen on a daily basis.

Category 4 occurs much less frequently, but is much more complicated to resolve because it requires software changes by the vendor.

Categories of Submission Problems

Problems in categories 1, 2, and 3 are seen on a daily basis. Category 4 occurs much less frequently, but is much more complicated to resolve because it requires software changes by the vendor.

References

• Straube et al., Digital Data Integrity QA for Multi-Institutional Advanced Technology Clinical Trials.