

Radiation Therapy Clinical Trials Digital Data Submission Overview

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Historical Review: RTOG Data Exchange Format

- Originated with:
 - AAPM Report #10
- Used and/or modified by:
 - NCI Particle Beam CWG
 - NCI External Photon Beam CWG
 - NCI External Electron Beam CWG
 - Image-Guided Therapy QA Center

Rationale for RTOG Data Exchange Format

- Advanced RT trials required an exchange method
- Relatively simple to implement
- Advanced RT trials pre-date DICOM-RT extensions
 - Influenced the development of RT extensions to DICOM 3.0

Digital Data for Advanced Technology Clinical Trials QA

- Primary Data (Archival)
 - Volumetric Images
 - Structures
 - Volumetric Dose Distributions
- Secondary Data (QA Support)
 - Plan Specification
 - Prescription/Verification images
 - DVHs

Necessary information for Clinical Trials QA and analysis

Images are basis for targeting, modeling and for dose calculation.

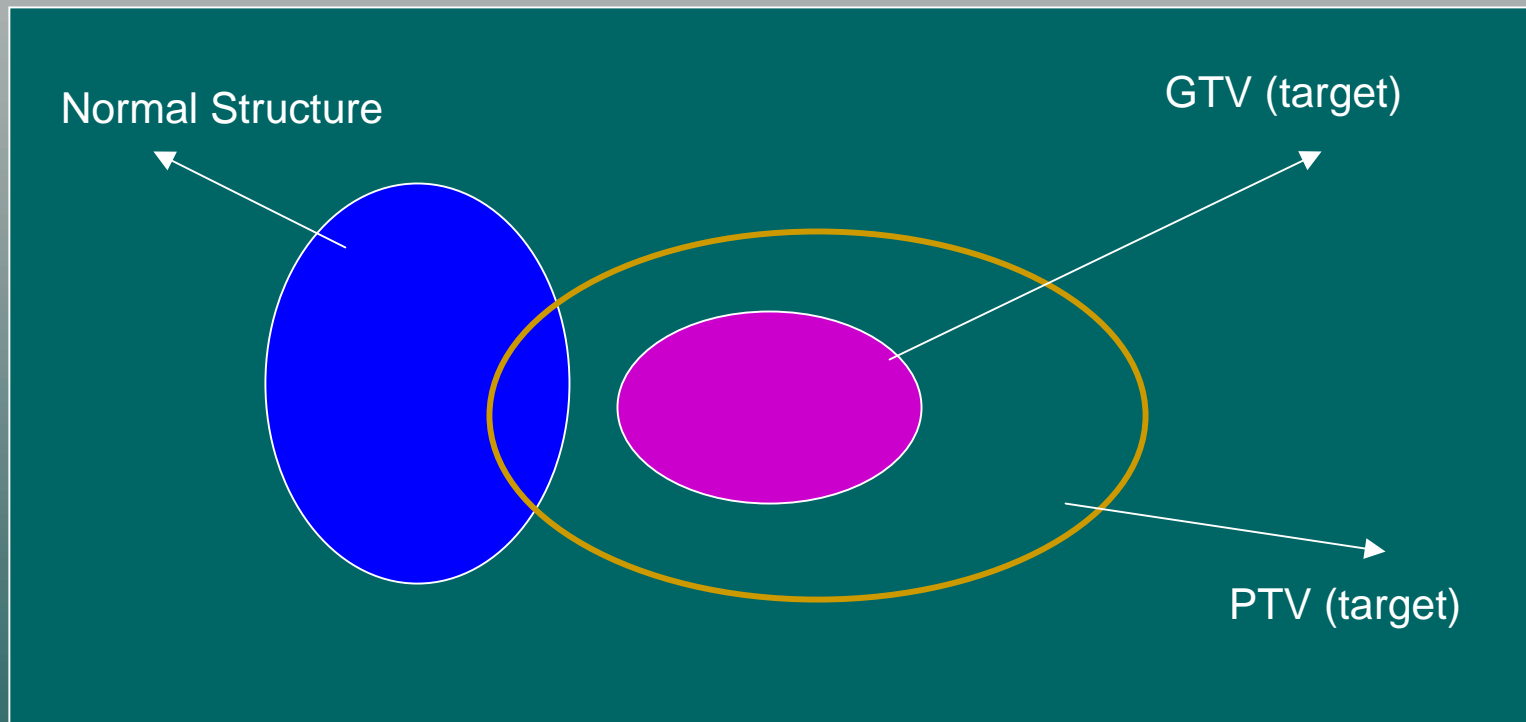
- CT's (and other) images
 - **Ensure protocol imaging requirements met.**
 - **Capture 3D anatomy for later data mining and analysis.**
- Other images
 - MR's
 - PET
 - Ultrasound

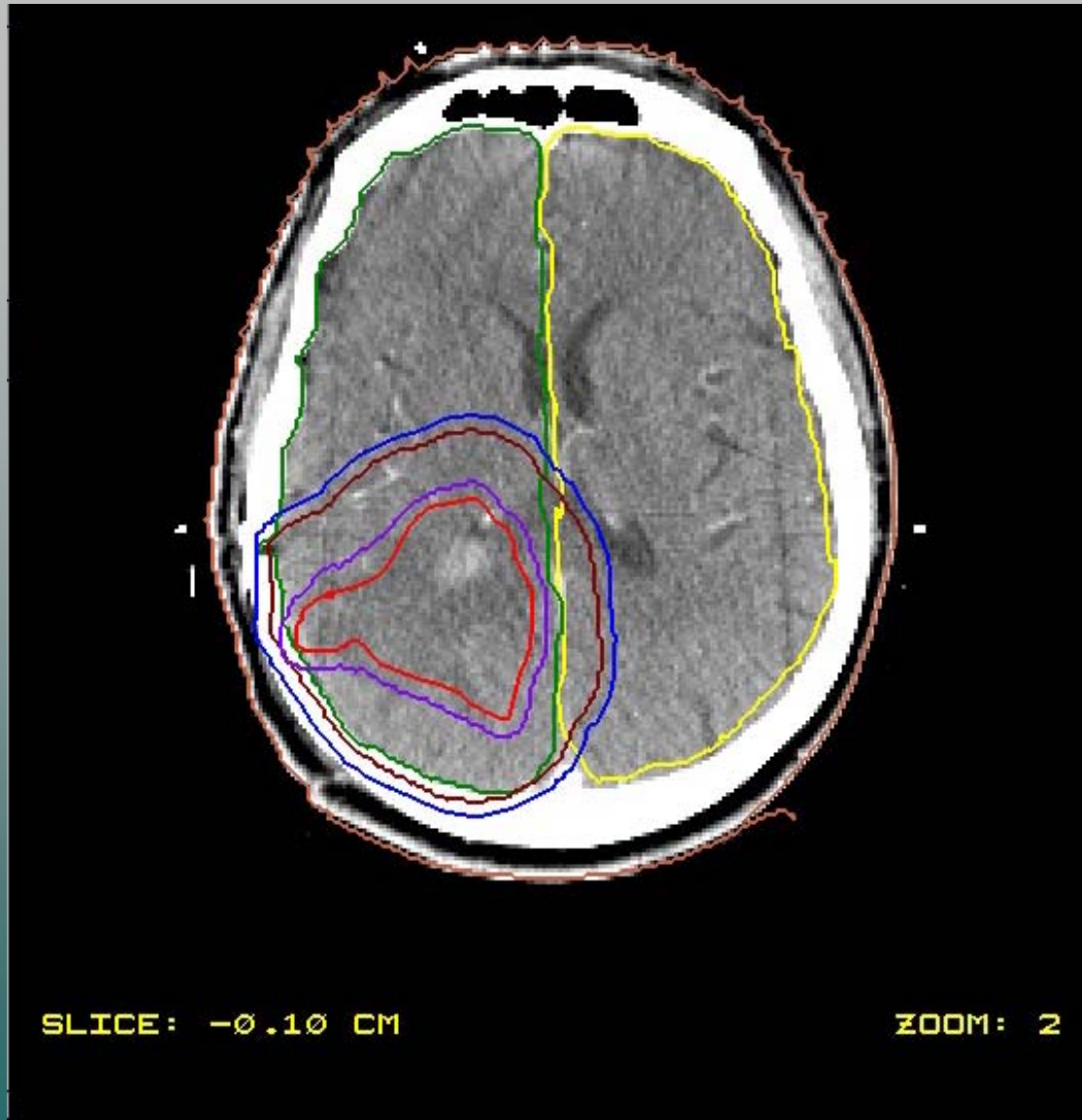
Necessary information for Clinical Trials QA and analysis

- **Structures**

- Ensure image segmentation is consistent with protocol (as segmented by the clinician).
- Allows recalculation of Dose Volume statistics using the 3D dose matrix.
- 2/3 of QA effort involves structures.

Need Ability to submit nested and overlapping structures





Necessary information for Clinical Trials QA and analysis

- **Volumetric Dose Data**
 - Used with contours allows recalculation of DVH's. This is done presently at ITC to assure consistency between cases and protocols.
 - Useful in toxicity and tumor control modeling (MDAH)
 - Useful in retrospective data mining (Penile Bulb study)

Necessary information for Clinical Trials QA and analysis

- **Beam geometry, permanent seed implant data, HDR data (Required except for IMRT)**
 - Ensure planned delivery consistent with protocol
 - Recalculation potential

Necessary information for Clinical Trials QA and analysis

- **DRR and port films**
 - Ensure that treated fields are the same as planned fields
 - Has been de-emphasized recently for individual case QA.

ITC QA Process

- Data Submission
- Data Extraction
- Data Preparation
- Data Review
- QA data storage

Data Submission:

RTOG data exchange/DICOM using

- FTP
- DAT (4 mm) Tape
- CD
- WebSys

Data Extraction

- CTs, Structures, Beams (Seeds), Dose, DVHs Extracted into a proprietary database for viewing with TPS or ITC developed tools.
- Individual fraction groups named.
- Upfront trouble shooting.
 - Data Errors noted and investigated.
 - Data Inventoried
 - Cursory Review of protocol compliance

Data Preparation

- Structures renamed.
- Combine individual fraction groups.
- DVH's recalculated.
 - Standard names
 - Standard Engine
 - Summed Dose

Remote Data Review

- Structures Reviewed, scored, and corrected
- DVH's recalculated.
- Dose Volume analysis review.

QA scoring

- Scores for structures entered in relational database with comments
- Dose volume analysis loaded into relational database.

