Roles of Medical Physicists in Radiation Therapy Trials

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Disclosures

• Receive research grants from NIH and Varian Medical Systems
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Outlines

Credentialing is one of the key processes for an institution to participate a clinical trial, which is to ensure the institution has the infrastructure, resources, and mechanism/culture to successfully conduct the designed clinical trials.

This presentation will discuss how a medical physicist can
• find credentialing information
• perform credentialing processes: initial credentialing, maintenance and ongoing credentialing
• identify challenges in the processes of credentialing
Resources for Credentialing and QAs

https://www.nrgoncology.org/

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Frequently Asked Questions

CT2 Daily Newsletter

https://clinicaltrials.gov/ct2/home

Medical Physics Section in NRG

• Review protocol draft versions and recommend changes
• Establish relationship with PIs for goals and technical consensus
• Become a resource to answer technical questions from institutions
• Participate in reviewing credentialing for the protocol
• Present progress reports of the protocol
• Participate, as needed, data review and case review
• Participate in manuscript preparation
• Recommend secondary analysis studies for the protocol

Credentialing Consideration

• IROC in US is NCI-sponsored and cooperative groups for dosimetric and physics credentialing

http://rpc.mdanderson.org/RPC/home.htm
Essentials for Conducting Clinical Trials

- A team approach:
  - Physicians (both radiation oncology and other specialists)
  - Physicists
  - Statisticians
- Set common standard
- Establish common criteria
- Perform credentials
- Maintain QA programs
- Maintain and monitor data collection
- Outcomes studies

Credentialing Consideration

- Protocol specific
- Treatment unit requirements
- Imaging and motion management specifications
- Planning system requirements
- Delivery technique specifications
- Immobilization requirements
- Simulation requirements
- Verification requirements
- Data management requirements

Credential through Phantom Study

http://rpc.mdanderson.org/rpc/
Technical Challenges between Centers

- Treatment machines
  - Different machines and calibration methods
  - Irradiate provided TLD or other dosimeters for QA control
- Treatment techniques
  - Different planning systems, calculation algorithms, margins, and prescription methods for 3D-CRT, IMRT
  - Pass specified IMRT phantom planning and QA test
- Treatment accuracy
  - Different verification methods, IGRT, portal images
- New technologies are rapidly being implemented

Planned vs. Prescription Dose

![Planned vs. Prescription Dose](Das et al. JNCI, 2008)

Physics Challenges for Credentialing Clinical Trials

- Staffing and resources
  - Staffing shortage
  - Staff training
  - Resources: equipment, device, data management
- Quality assurance
  - Equipment
  - Consistency
How to Meet QA Requirements

- Establish a well-defined QA program
- Follow the recommendations and guidelines of government and professional organization
- Develop QA protocols for each procedure
- Assign responsibility to individuals/group
- Document QA materials for audit
- …..

Quality Assurance (QA)

- Facility-specific QA
- Equipment-specific QA
- Patient specific QA
- Process specific QA

Facility-Specific QA: General

- Facility infrastructure
- Equipment
- IT and data management
- Staffing
- …..
### Equipment-Specific QA: General

- **System and devices**
  - Delivery system
  - Imaging system
  - Planning system
  - Immobilization system
  - Measurement devices
  - Motion management devices
  - ...
- **Protocols – AAPM TGs**

### Device-Specific QA: Isocenter Concurrence

**Consistency of Imaging and Delivery**

<table>
<thead>
<tr>
<th>DVH changes</th>
<th>5 mm shifts</th>
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</thead>
<tbody>
<tr>
<td>Delivery system</td>
<td>Imaging system</td>
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### Patient-Specific QA: Positioning Accuracy

**Three-step verification:**

- **A** - Prior to correction
- **B** - After correction before treatment
- **C** - After treatment

RTOG0631, Yin et al TCRT 2008
**Process-Specific QA: General**

![Diagram showing patient and QA processes](Image)

Salama, Kirkpatrick, and Yin
Nature Reviews/Clinical Oncology 2012

**Process-Specific QA: Details**

**Issues related to operational tasks:**
- The protocol development process – appropriate approval process
- SOPs to execute the protocols
- SOPs to document and report the data and results
- Staffing level is appropriate
- Staff training and continuous training are available and appropriate
- Proper follow-up actions are taken for any actual and/or potential (“near miss”) treatment incidents

**Procedure-Specific QA: 4DCT Artifact**

![Image showing Mismatched signals](Image)
Summary

• A unified standard needs to be developed and adopted for credentialing of clinical trials
• Adequate staffing and resources are required
• A mechanism for monitoring credentials should exist
• Multi-dimensional QAs, including IGRT QA are essential and challenging but should be considered

Thank you for your attention