**NCI Clinical Trial Reorganization**

<table>
<thead>
<tr>
<th>Current Groups</th>
<th>March 1, 2014</th>
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<tbody>
<tr>
<td>RTOG</td>
<td>NRG Oncology</td>
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<td>NSABP</td>
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<td>GOG</td>
<td>Alliance</td>
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<td>NCCTG</td>
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<td>CALGB</td>
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IROC Mission

Provide integrated radiation oncology and diagnostic imaging **quality control programs** in support of the NCI's NCTN Network thereby **assuring high quality data** for clinical trials designed to improve the clinical outcomes for cancer patients worldwide.

IROC Grant Status

- Grant review on July 16, 2013
- Excellent score and appropriate Summary Statement
- Award notice by 12/2013 (delayed due to gov't shutdown)
- Start date of no earlier than 3/1/2014
- All IROC components given administrative supplements for first 2 months in 2014.
**IROC Leadership Structure**

1. Site Qualification (FQs, ongoing QA, proton approval, resources)
2. Trial Design Support/Assistance (protocol review, templates, help desk, key contact QA centers)
3. Credentialing (tiered system to minimize institution effort)
4. Data Management (pre-review, use of TRIAD, post-review for analysis)
5. Case Review (Pre-, On-, Post-Treatment, facilitate review logistics for clinical reviews)

**Purpose:** manage IROC QA services/operations to ensure the uniform implementation of IROC core services, prioritization of core services and establish, in collaboration with the NCTN groups, future directions of IROC.
IROC’s NCTN RT Core Services

IROC – Site Qualification
1. Facility Questionnaire (on-line)
2. OSLD/TLD
3. Particle Beam Approval

Trial Concept and Protocol Consultation Key Contact Offices

<table>
<thead>
<tr>
<th>NCTN Group</th>
<th>Radiation Oncology</th>
<th>Imaging</th>
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<tbody>
<tr>
<td>Alliance</td>
<td>Rhode Island</td>
<td>Ohio</td>
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<td>COG</td>
<td>Rhode Island</td>
<td>Rhode Island</td>
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<tr>
<td>ECOG/ACRIN</td>
<td>Rhode Island</td>
<td>Philadelphia (I)</td>
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<tr>
<td>NRG Oncology</td>
<td>Philadelphia (RT)</td>
<td>Philadelphia (I)</td>
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<td>SWOG</td>
<td>Rhode Island</td>
<td>Ohio</td>
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Houston will be reviewing all patients treated with brachytherapy
IROC - Credentialing

Tier 0
Update protocol appropriate information on FQ and data transfer capability
Tier 1
Protocol Specific KA, Pre-Treatment review of 1st patient only, EXBT and Brachytherapy Benchmarks
Tier 2
Independent measurement of treatment deliveries
Tier 3
This tier is reserved for protocols that push the limits of the lower tiers

IROC – Data Management

1. Management of data both pre-review and post-review
2. Common data entry site – TRIAD
3. RAVE – what data should be captured and review of data entered correctly
4. Post-review for analysis

IROC – Case Review

Patient Case Clinical and Technical Reviews

Pre-Treatment (formerly Rapid Review)
On-Treatment
Post-Treatment (formerly Retrospective Review)

IROC facilitates the logistics and data organization for the clinical reviews.
Groups will supply clinicians.
Summary

- IROC RT QA centers have decades of experience, knowledge and infrastructure.
- Protocol review as early as possible is critical to establishing appropriate QA procedures.
- Patient case reviews require IROC and Groups to work together.
- RT and Imaging are working closely together.
- Collaboration and feedback from NCTN Groups is required.
- Groups to have complete accessibility to data.
Thank You
Questions?