

The Imaging and Radiation Oncology Core (IROC) Cooperative's Activities Supporting the NCI's National Clinical Trial Network.

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Purpose/Objective: The Imaging and Radiation Oncology Core (IROC) Cooperative has been active for the past two years supporting the National Clinical Trial Network (NCTN) and the details of that support are reported. The objective of this work is to describe the numerous activities accomplished by IROC over the past two years in support of NCI's NCTN clinical trials.

Material/Methods: IROC is made up of six QA centers (Houston, Ohio, Philadelphia-RT, Philadelphia-DI, Rhode Island, St. Louis) providing an integrated RT and DI quality control program in support of the NCI's clinical trials (Figure 1).

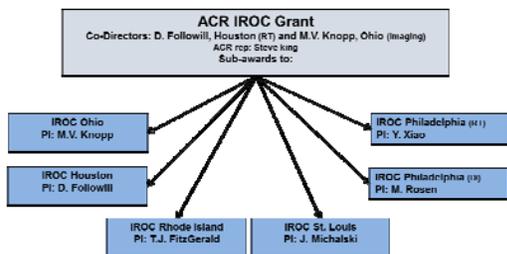


Figure 1. IROC QA Centers and their PIs.

The QA Center's efforts are focused on assuring high quality data for clinical trials designed to improve the clinical outcomes for cancer patients worldwide. This program is administered through five core services: site qualification, trial design support, credentialing, data management, and case review.



Each QA center has its own responsibilities that minimize redundancy, rely on existing infrastructure and increase efficiency. IROC QA Centers have been assigned to support the 5 different NCTN groups based on past established relationships.

IROC QA Centers Key Support

NCTN GROUP	RADIATION ONCOLOGY	IMAGING
Alliance	Rhode Island	Ohio
COG	Rhode Island	Rhode Island
ECON-ACRIN	Rhode Island	Philadelphia (DI)
NRG Oncology	Philadelphia (RT)	Philadelphia (DI)
SWOG	Rhode Island	Ohio

Results: IROC currently provides core support for **172** NCTN trials with RT, DI and RT/DI components (Table 1). Many of these trials were legacy trial from the previous cooperative group program.

IROC QA Center	No. of RT Trials	No. of Imaging Trials	No. of RT/I Trials
Houston	64	0	0
Ohio	0	33	8
Philadelphia – DI	0	14	8
Philadelphia – RT	30	0	9
Rhode Island	32	11	23
St Louis	9	0	1

Table 1. The number of trials with RT, Imaging or RT plus imaging supported by each QA center.

SITE QUALIFICATION

IROC monitors nearly **1800** RT photon and **20** proton institutions in 28 different countries. Over **28,000** beams outputs were monitored these past two years with 8% of the sites requiring repeat audits due to a beam outside of the 5% criterion.

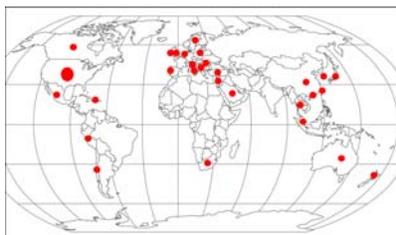
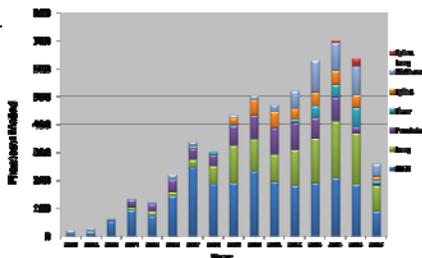


Figure 2. Countries with one or more RT centers monitored by IROC QA Centers.

CREDENTIALING

As part of credentialing, **950** QA phantoms have been irradiated, **515** imaging modalities evaluated and almost **4000** credentialing letters have been issued over the past two years.



Results:

DATA MANAGEMENT

In just year 2 of the IROC activities, **5290 RT** and **4934 DI** patient datasets were received (many using TRIAD) by IROC QA Centers to be prepared for review.

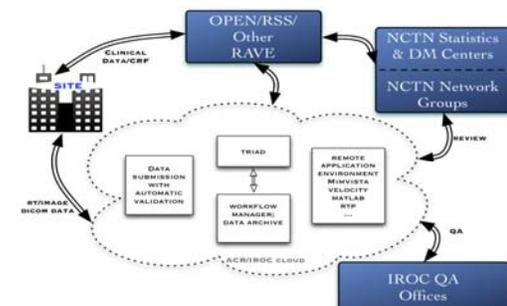


Figure 3. Patient data flow/review for NCTN clinical trials that includes TRIAD.

CASE REVIEW

During the past 2 years, **6300 RT** cases and **19,000 DI** image sets were reviewed by IROC technical staff for quality and interpretation. It is IROC's responsibility to prepare the data and ensure it's completeness while it is the NCTN Group's responsibility to interpret the cases as per protocol or deviation. MiM software is often used often for DVH and clinical evaluations.

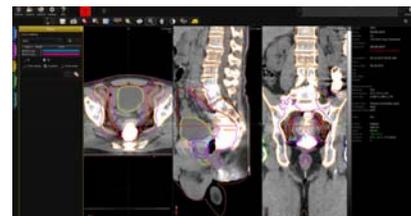


Figure 4. Screenshot of MIM software used for case analysis.

Conclusion: The QA services provided by IROC are numerous and are continually being evaluated for effectiveness, harmonized across all NCTN Groups and administered in an efficient/timely manner to enhance accurate and per protocol trial data submission.

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