

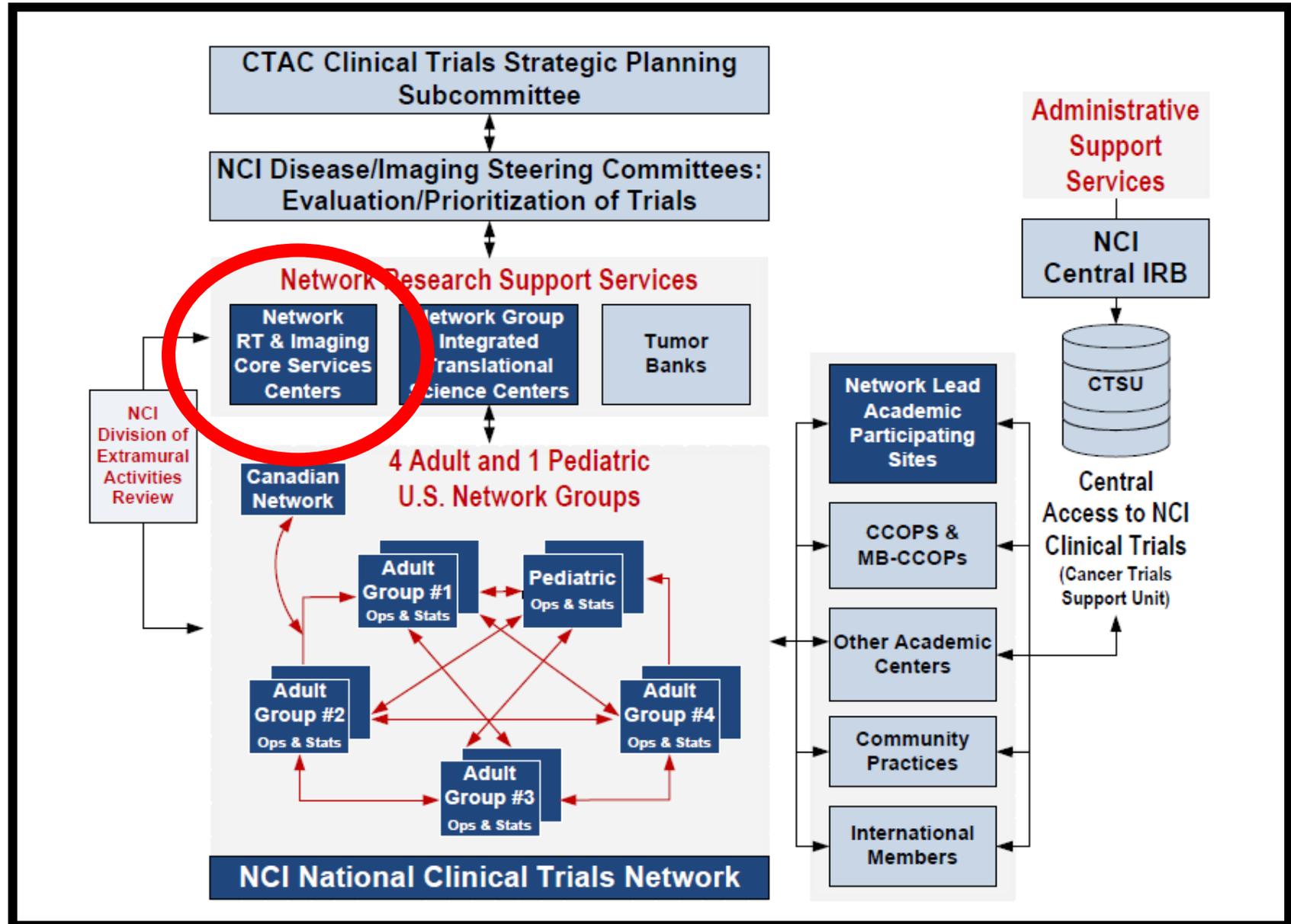
The Imaging and Radiation Oncology Core (IROC) Group: A Proposed New Clinical Trial Quality Assurance Organization

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NCI Clinical Trial Reorganization



Clinical Trial Groups

Current

March 1, 2014

RTOG

NSABP

GOG

NCCTG

CALGB

ACOSOG

ECOG

ACRIN

SWOG

COG



NRG Oncology



Alliance



ECOG/ACRIN



SWOG

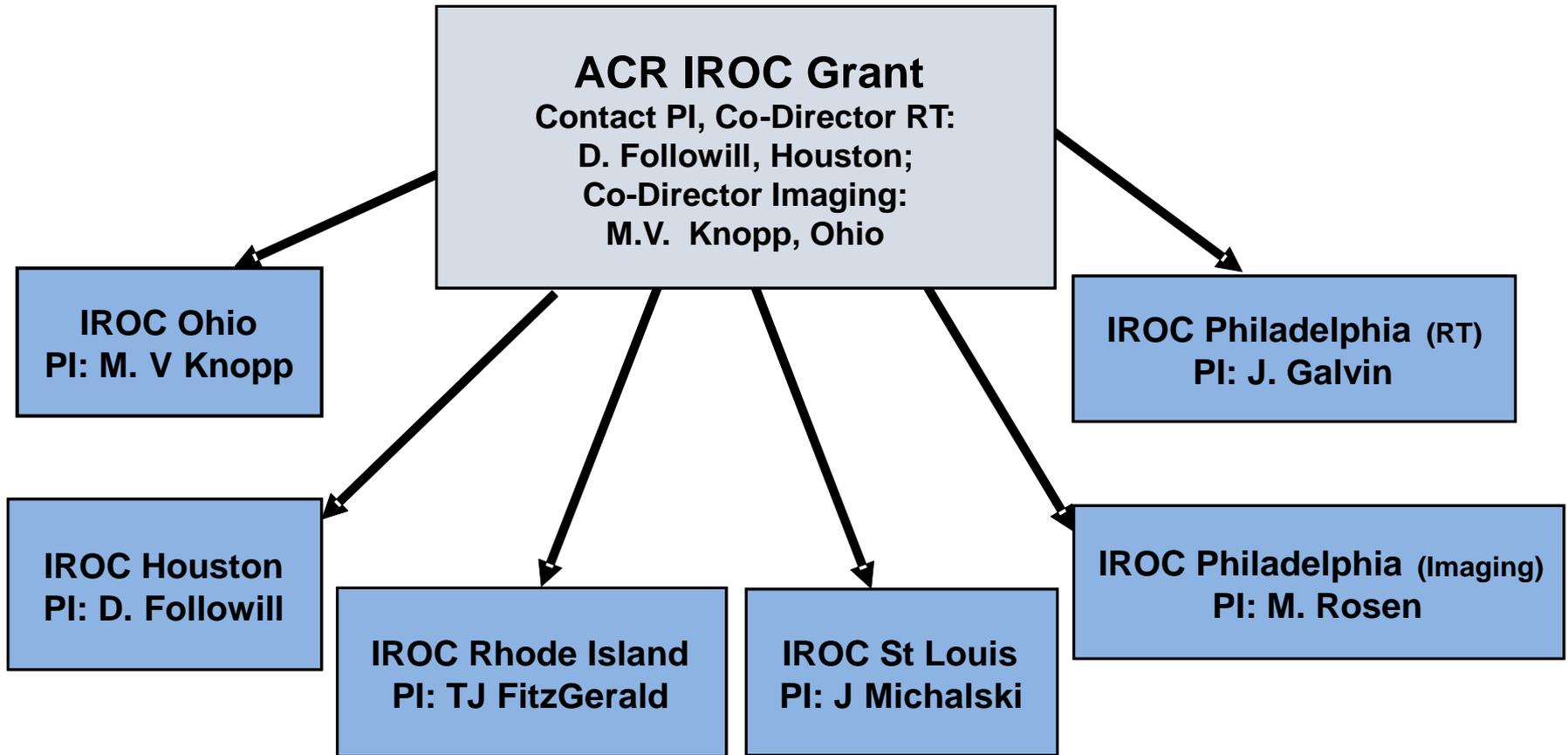


COG

IROC Grant Process

- Grant submitted 1/15/2013 to NCI through the ACR (398 page document)
 - Proposes 6 QA centers with multiple PIs
 - Budget of \$15M for first year (6 QA centers)
 - Followill - Contact PI and IROC Co-Director (therapy)
- Review on July 16, 2013
- Award notice by 11/2013
- Start date of no earlier than 3/1/2014
- RPC grant ends 12/31/2013 (administrative extension until new grant begins)

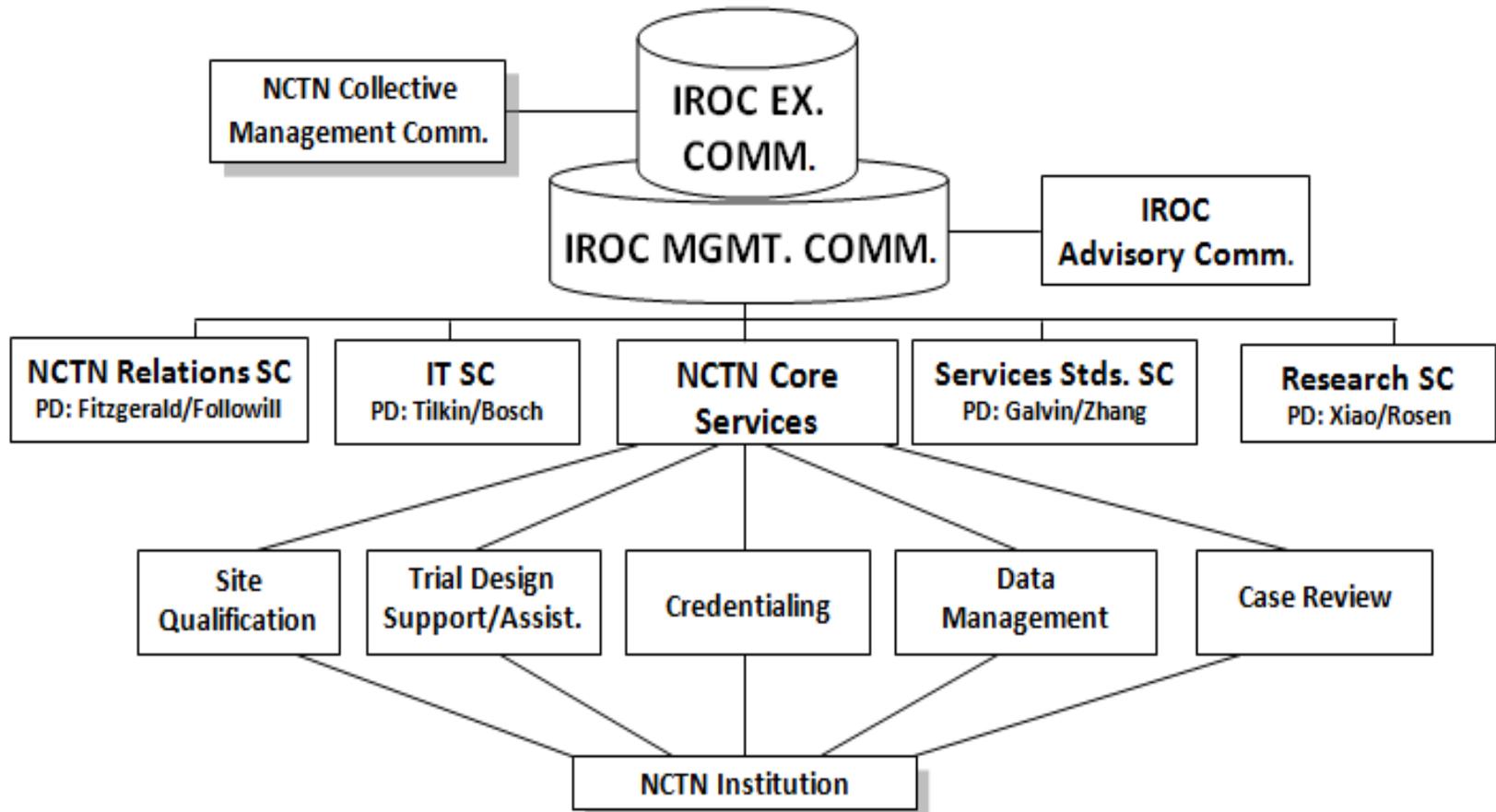
Members of IROC



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 Leadership Structure



IROC Management Committee

Six IROC PIs

IROC Subcommittee co-chairs

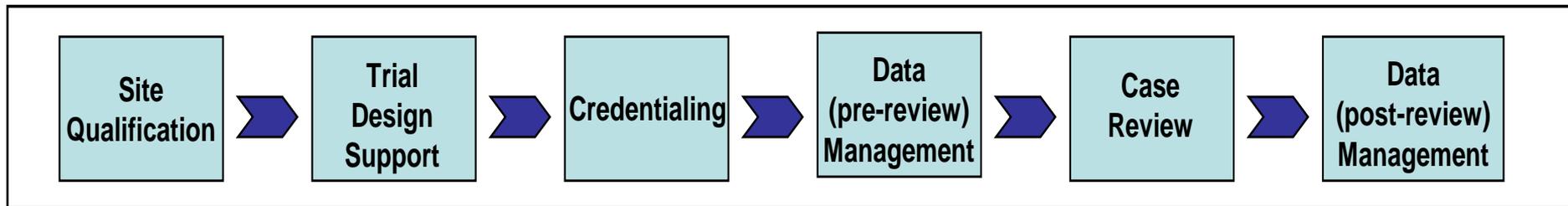
IROC administrators

IROC key staff (RT and imaging)

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

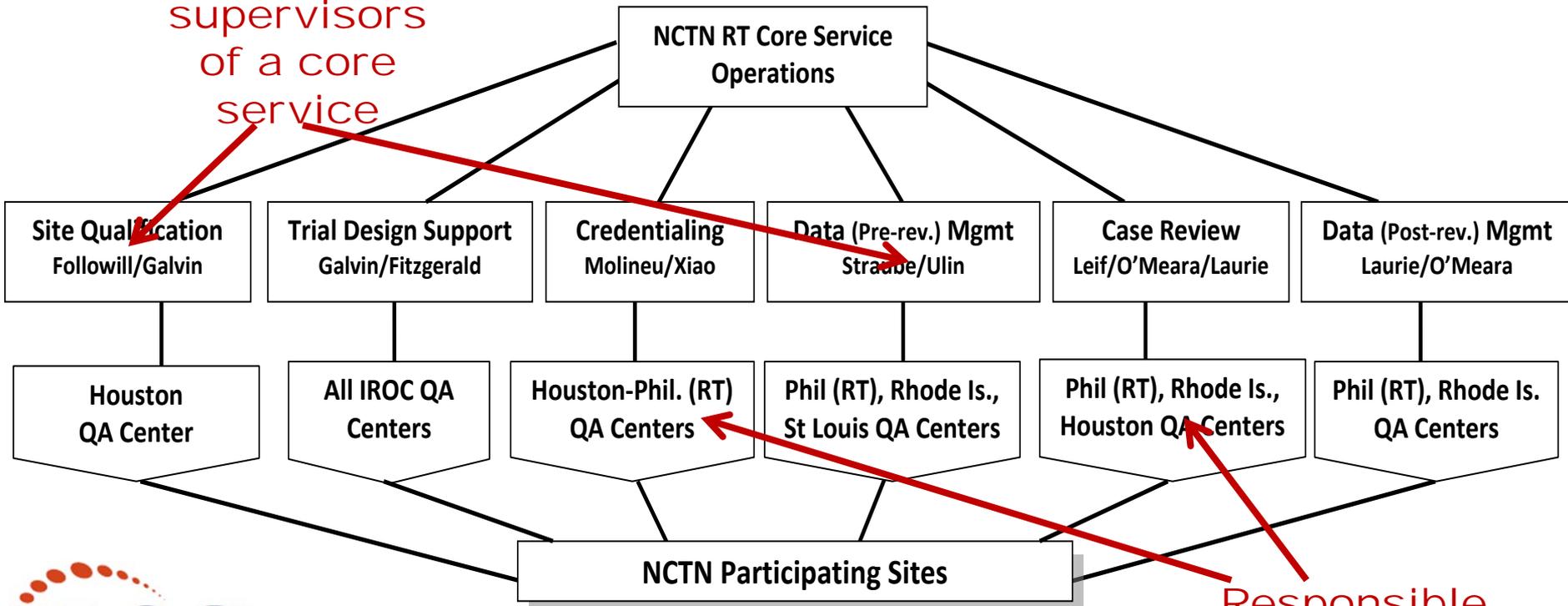
IROC's Five General NCTN Core Services

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)



IROC's NCTN RT Core Services

Principal supervisors of a core service



Responsible QA Centers for core service

Trial Concept and Protocol Consultation Key Contact QA Centers

NCTN Group	Radiation Oncology	Imaging
Alliance	Houston	Ohio
COG	Rhode Island	Rhode Island
ECOG/ACRIN	Rhode Island	Philadelphia (I)
NRG Oncology	Philadelphia (RT)	Philadelphia (I)
SWOG	Rhode Island	Ohio

IROC Services

Patient Case Clinical and Technical Reviews

Pre-Treatment

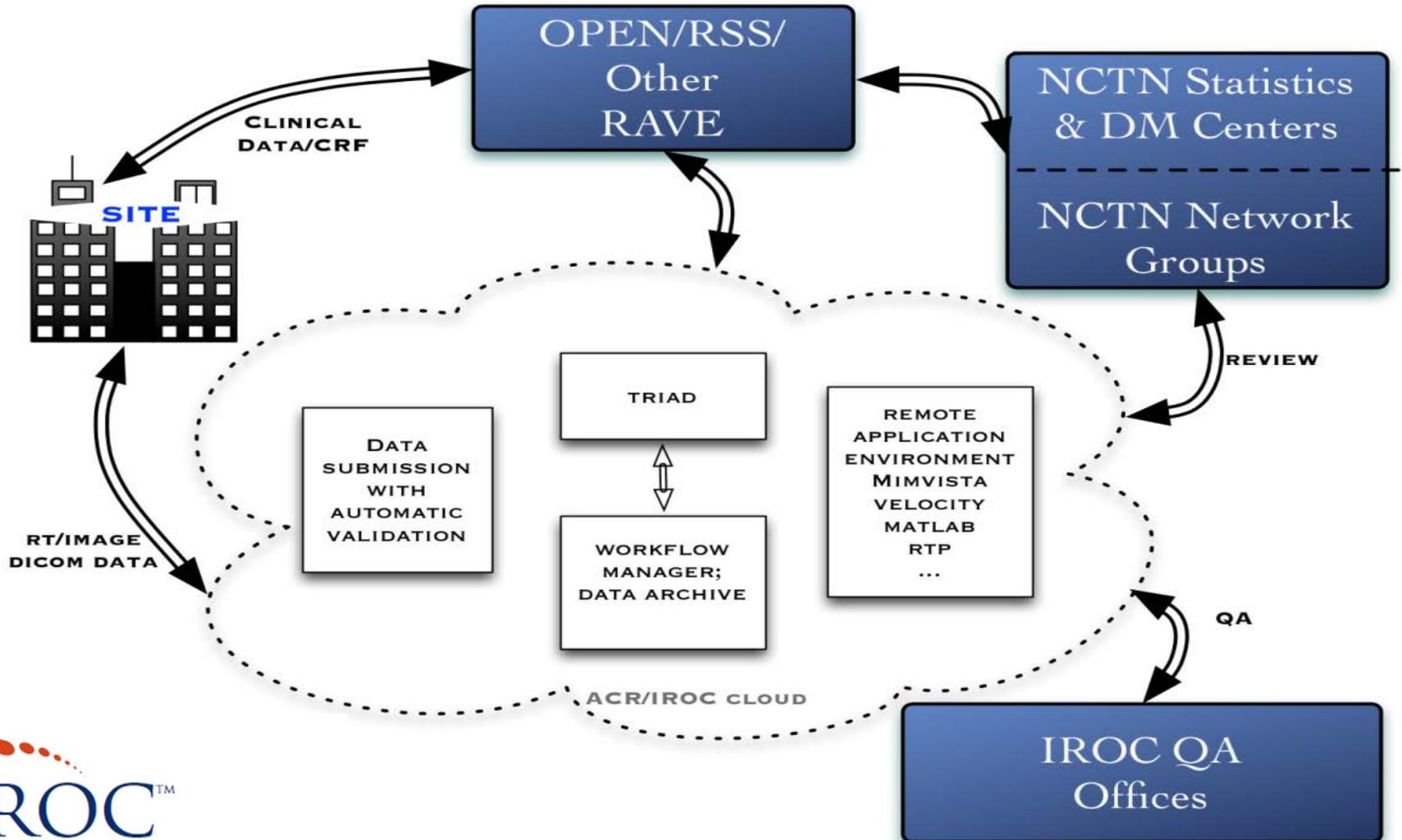
On-Treatment

Post-Treatment

IROC facilitates the logistics and data organization for the clinical reviews.

Study Groups will supply clinicians.

The ACR/IROC Cloud



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?