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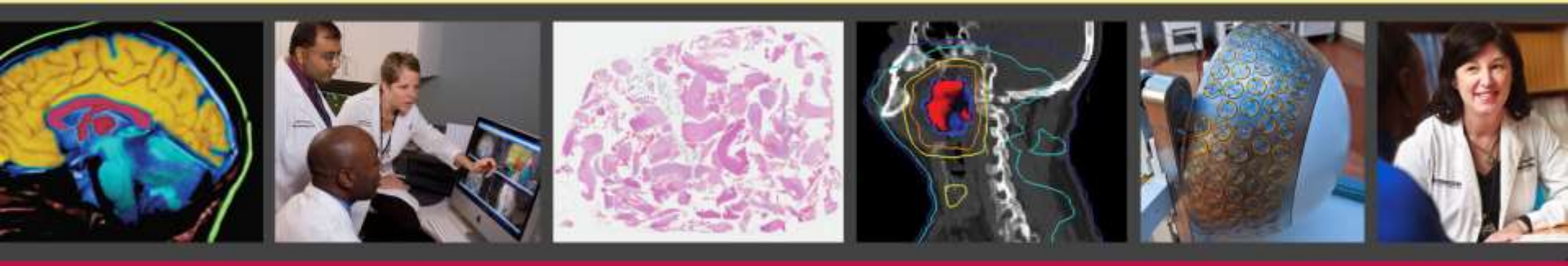
RADIATION THERAPY ONCOLOGY GROUP



Radiation Oncology Technology Exploration and Quality Assurance in Clinical Trials

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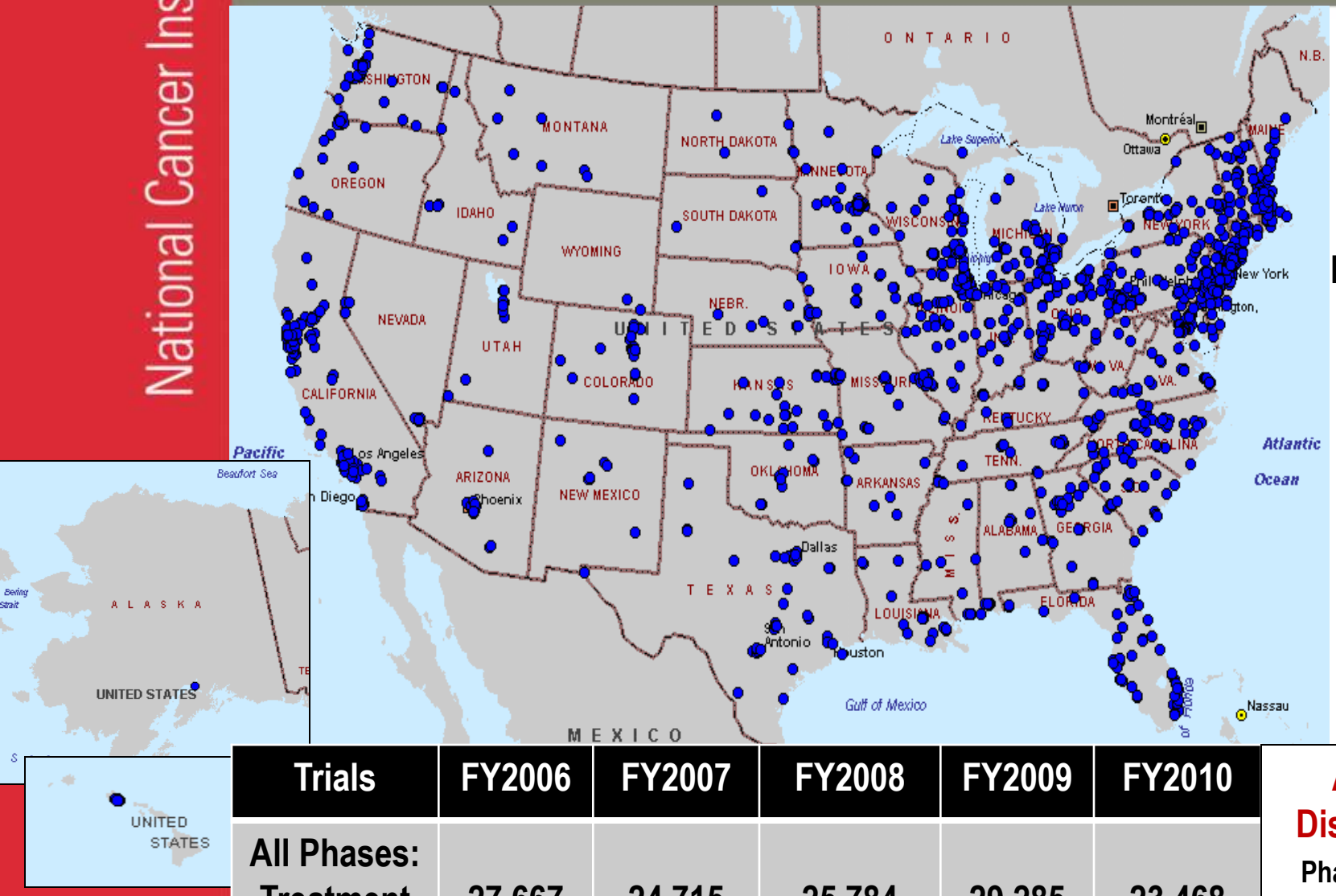
ACR AMERICAN COLLEGE OF RADIOLOGY

Objectives

- Describe NCI's Initiative to revamp the clinical trial system
- Present an overview of a proposed Imaging Radiation Oncology Core (IROC) services Group
- Describe the proposed Center for Innovative Radiation Oncology (CIRO) of NRG
- Introduce clinical trial technological exploration and quality assurance science

National Cancer Institute

Overview of the Current Program



3,100 Institutions

14,000 Investigators

About 25,000 pts enrolled on tx trials annually

Trials	FY2006	FY2007	FY2008	FY2009	FY2010
All Phases: Treatment Trials	27,667	24,715	25,784	29,285	23,468

Accrual Distribution:

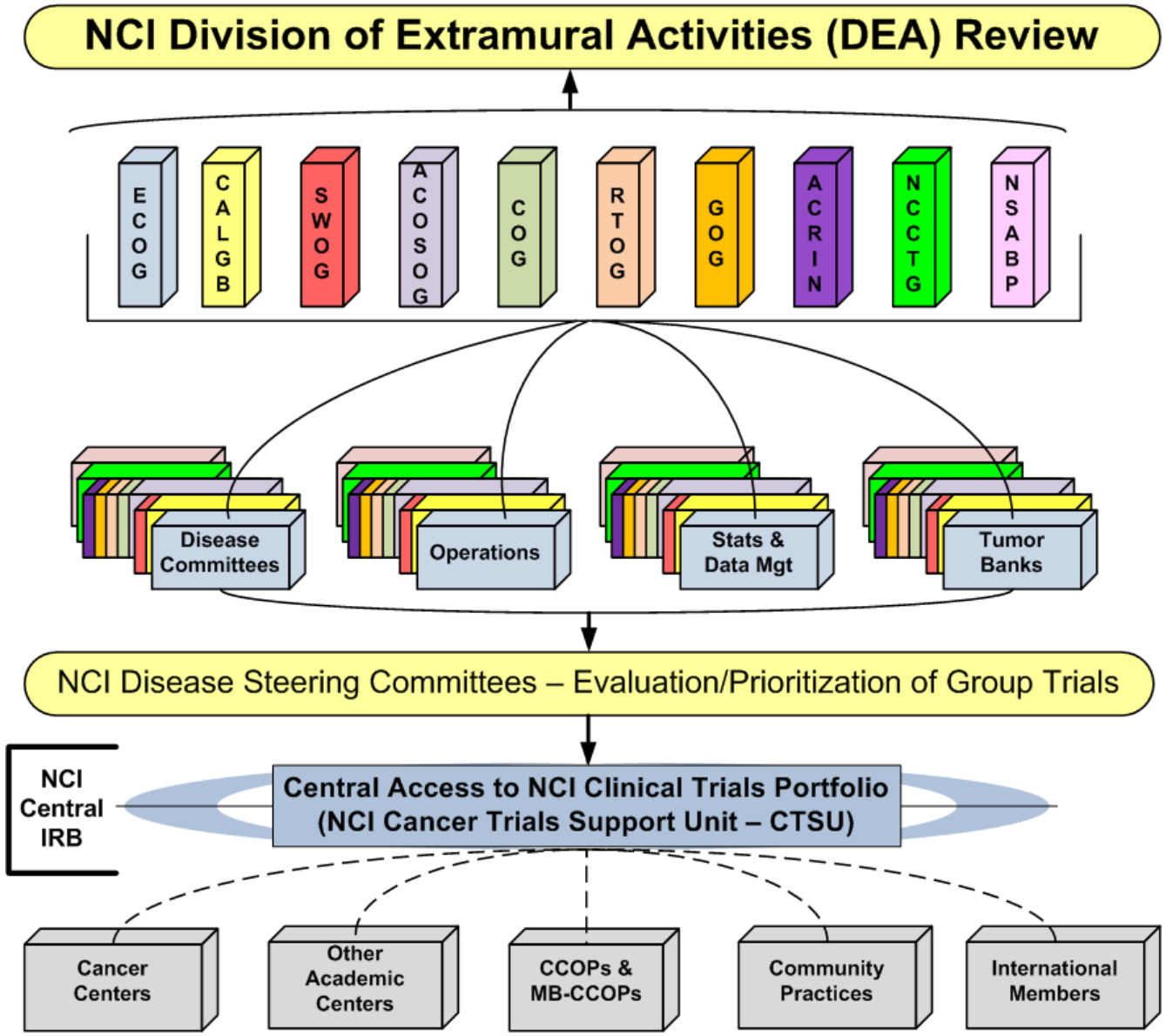
Phase 3: 83.4%

Phase 2: 15.1%

Phase 1/Pilot: 1.5%

National Cancer Institute

Structure of Program: As of January 2011



National Cancer Institute

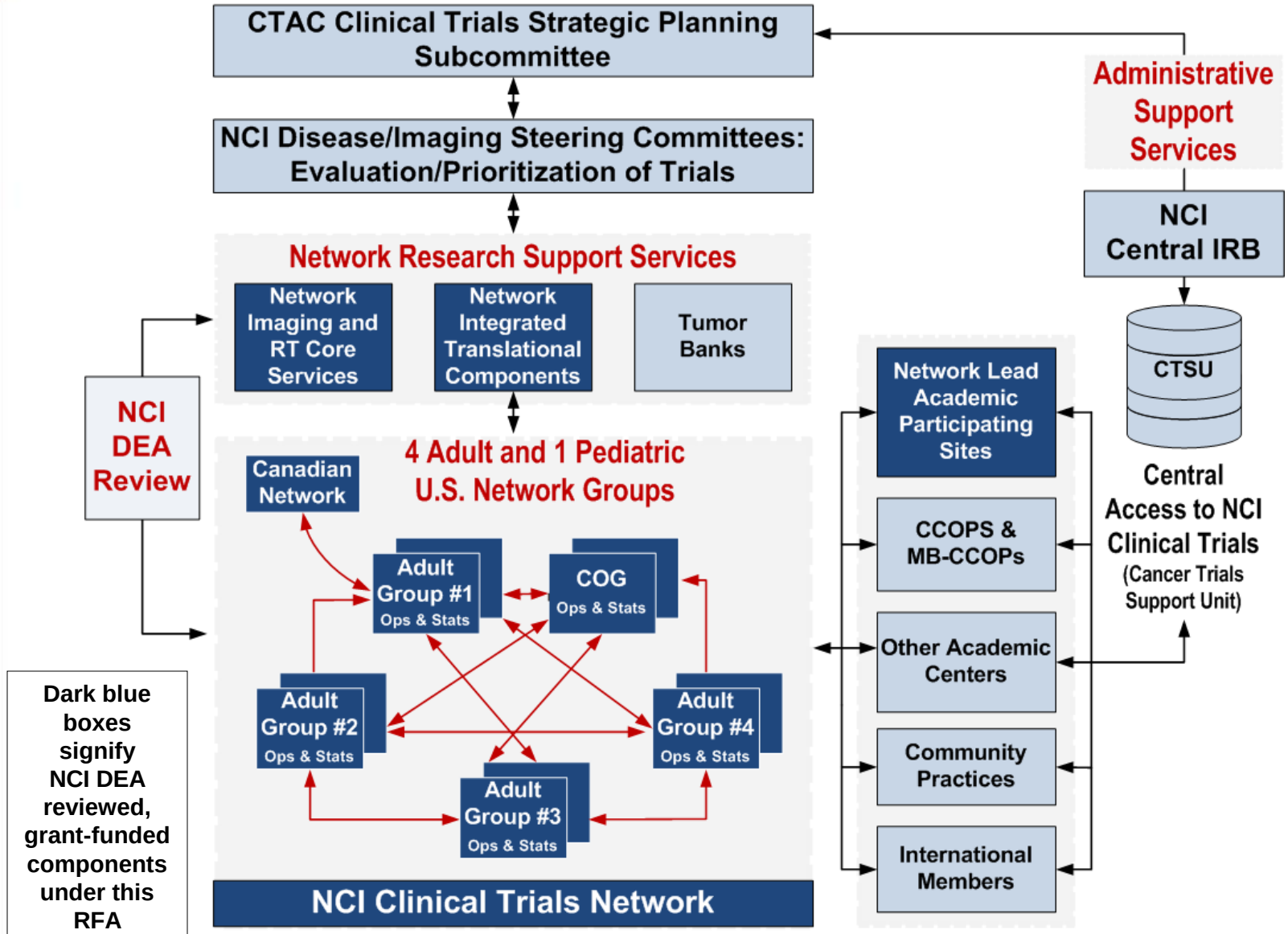
Rationale for Transforming Current Program:
How Will Consolidated Network System Help?

- **Consolidate infrastructure to gain efficiencies (e.g., IT, Regulatory, Administrative, Tissue Resource Management)**
- **Consolidate Imaging & RT core services to benefit entire Network**
- **Integrate new components into trials to provide value-added research questions (e.g., advanced imaging, translational science)**
- **Integrate new agents into trials**
  - **Ex: Erlotinib, crizotinib, & ipilimumab are being integrated into trials in earlier stages of lung cancer & melanoma treatment requiring screening large populations & combining the agents optimally with surgery, RT, and immunotherapy**
- **Evaluate new agents in molecularly-defined disease subsets**
  - **Ex: Even for common diseases such as breast cancer, # of molecularly-defined patient subsets is increasing & there is a need for trial prioritization evaluating multiple new agents with standard regimens across subsets to avoid duplication & optimize accrual**

http://deainfo.nci.nih.gov/advisory/ncab/161_0212/Abrams.pdf

National Cancer Institute

Introducing A New Organizational Structure
NCI Clinical Trials Network



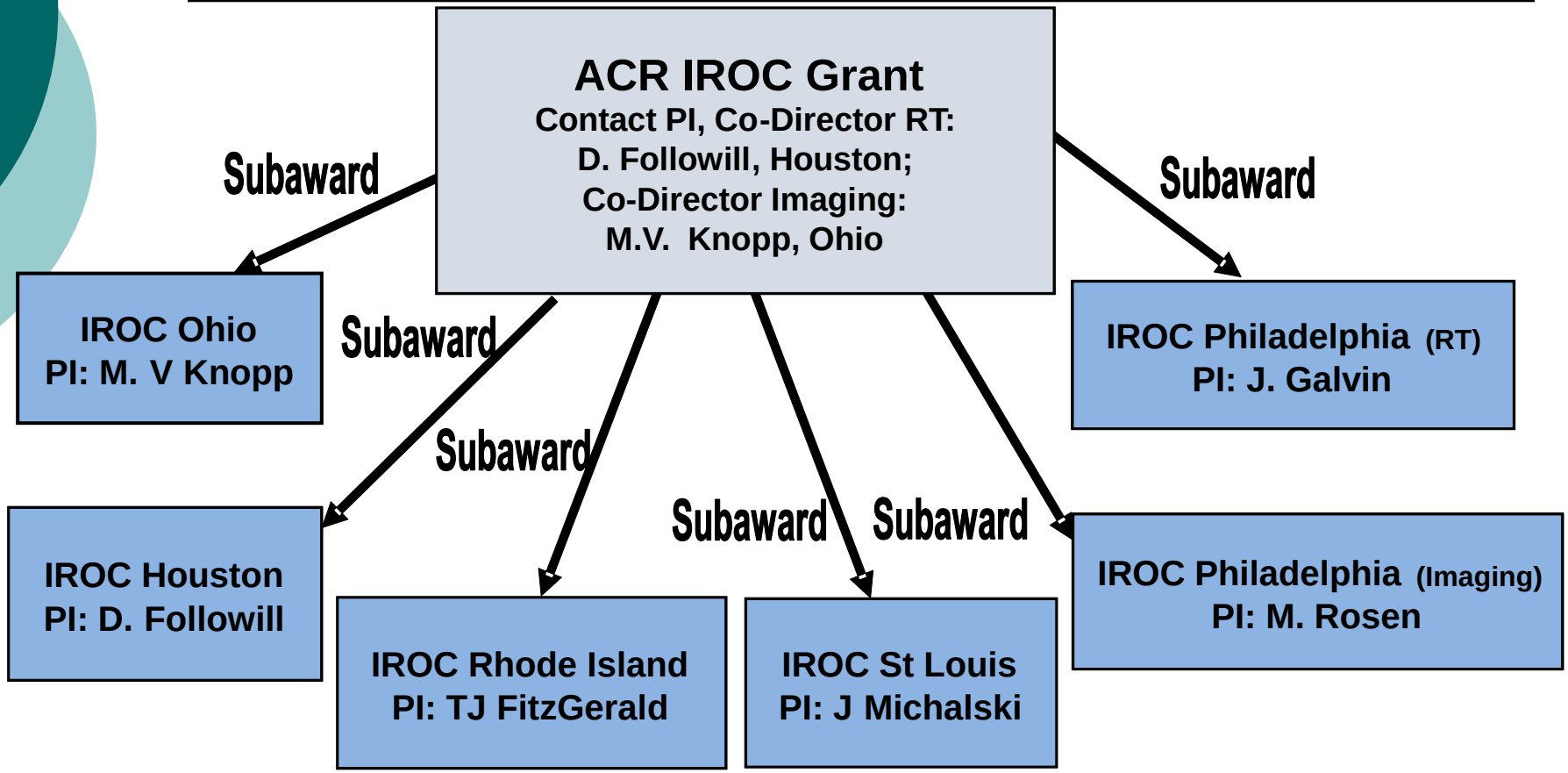
IROC

Imaging and Radiation Oncology Core Group

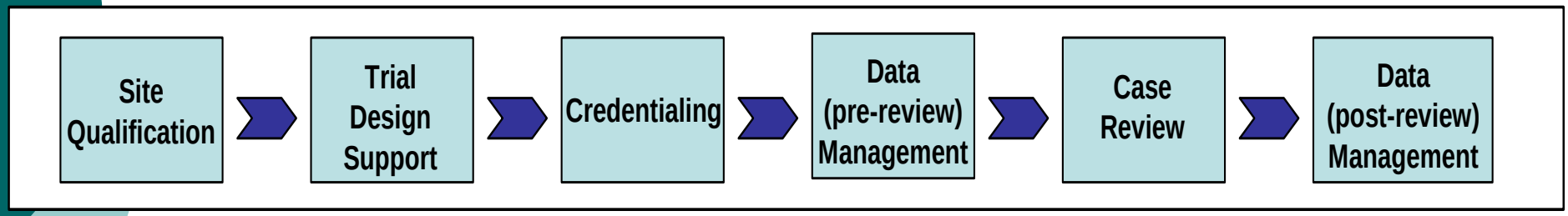
IROC Mission

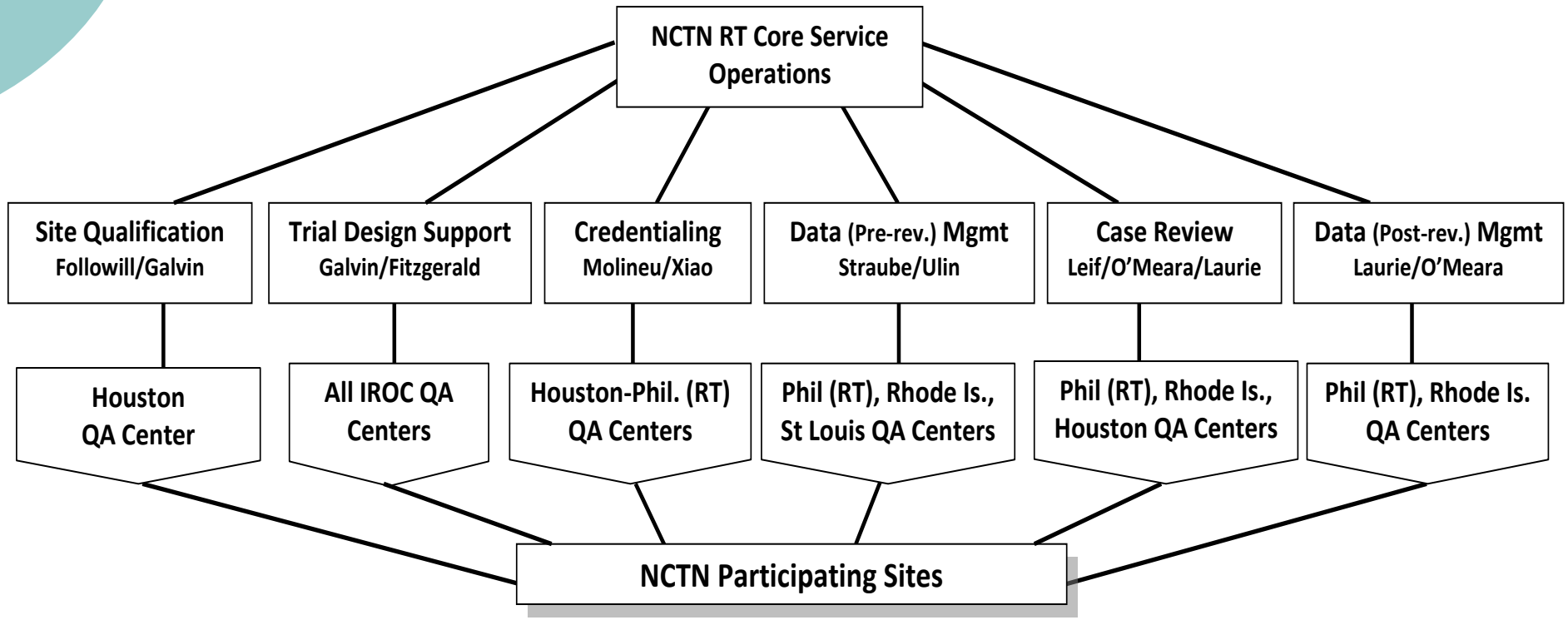
Provide integrated radiation oncology and diagnostic imaging quality control programs in support of the NCI's NCTN Network thereby assuring high quality data for clinical trials designed to improve the clinical outcomes for cancer patients worldwide

Members of IROC

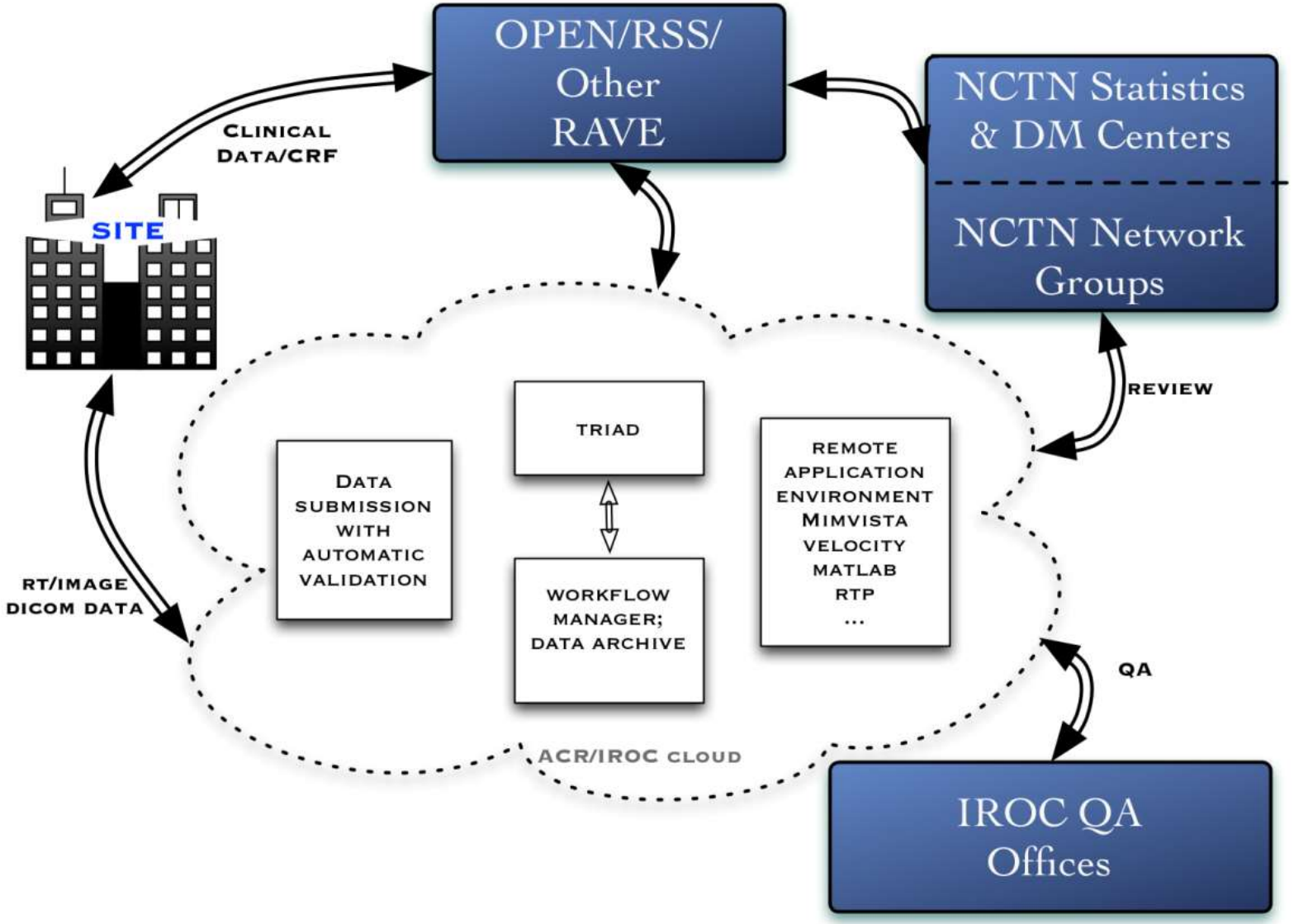


IROC's Five General NCTN Core Services

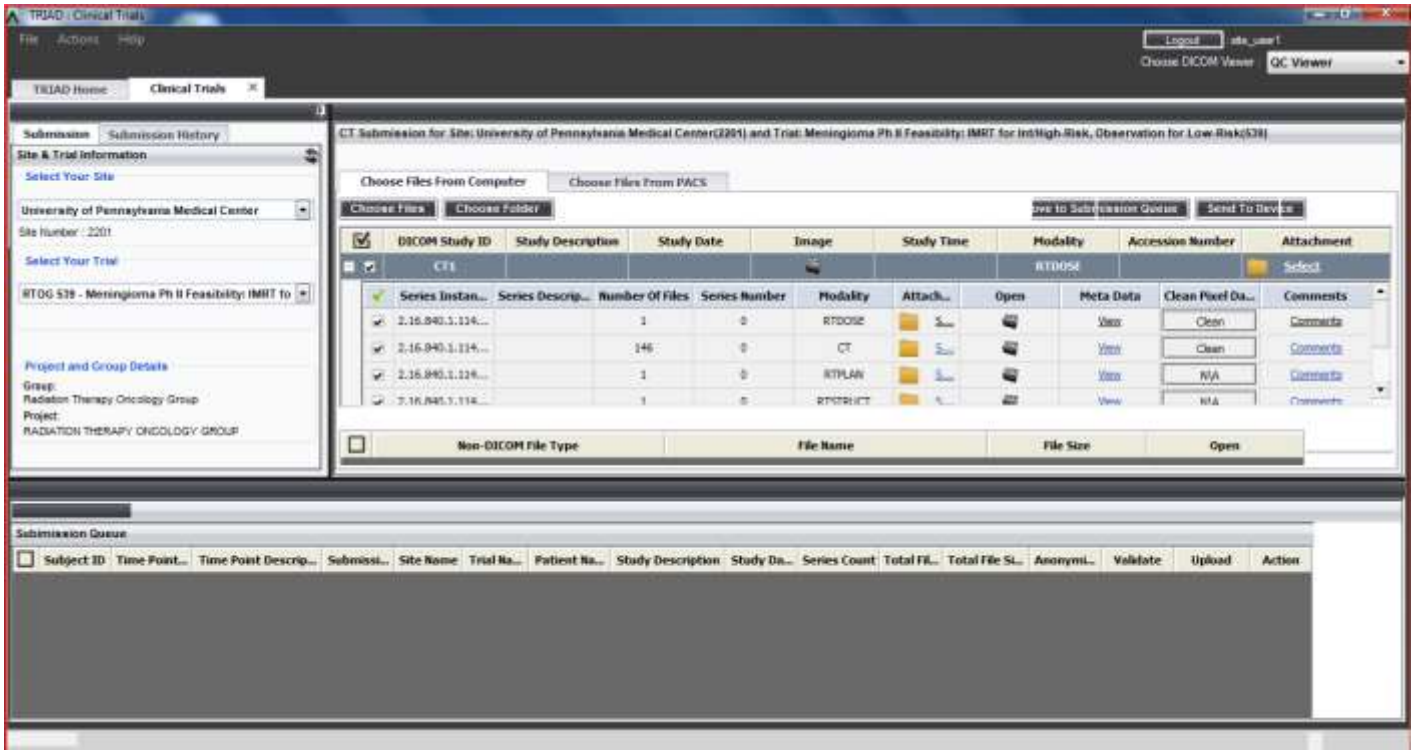




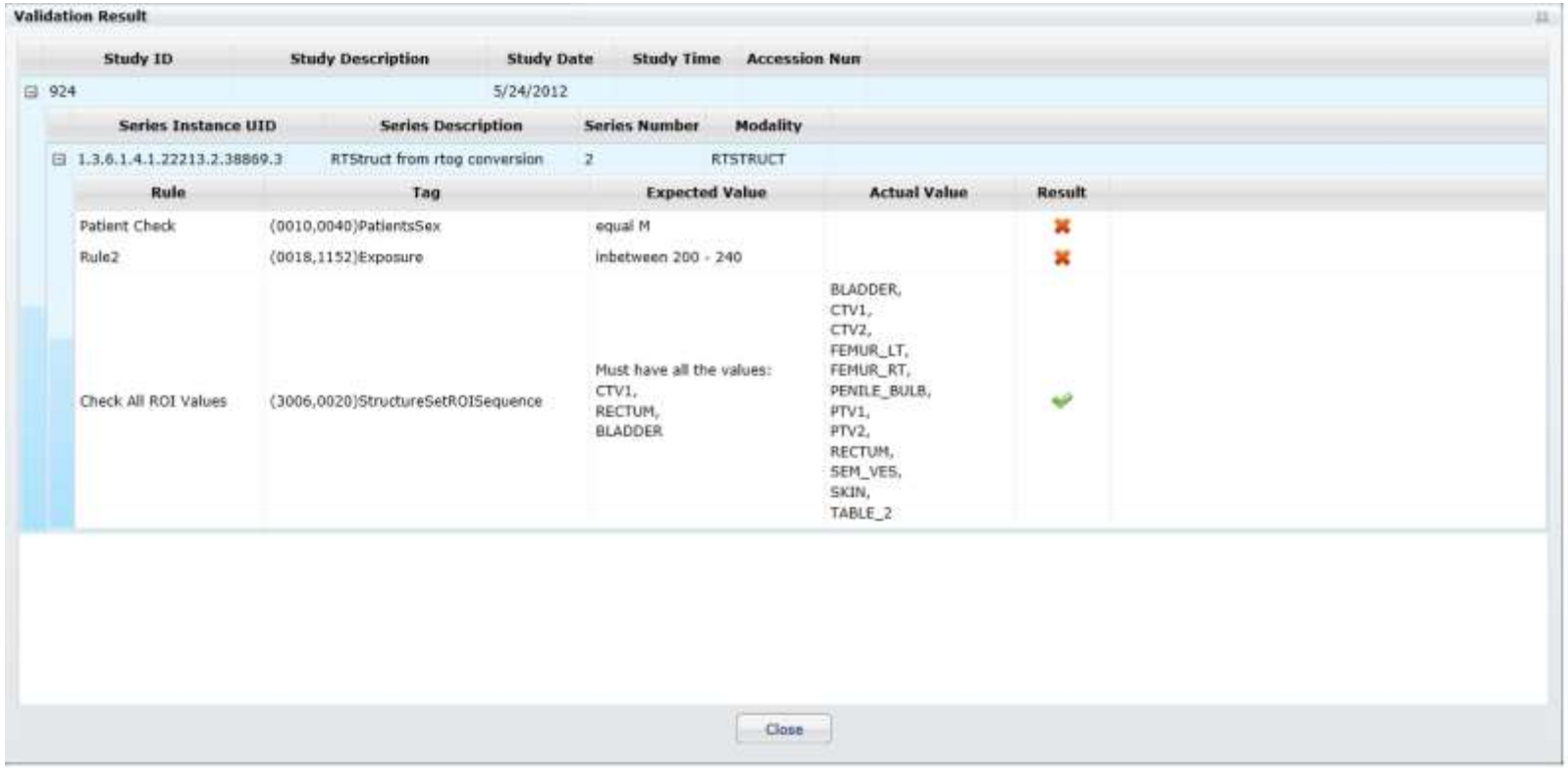
The ACR/IROC Cloud



Example:
Data Submission via TRIAD



Automated Validation



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 to work closely together.
- Collaboration and feedback from NCTN Groups is required.
- Groups to have complete accessibility to data.

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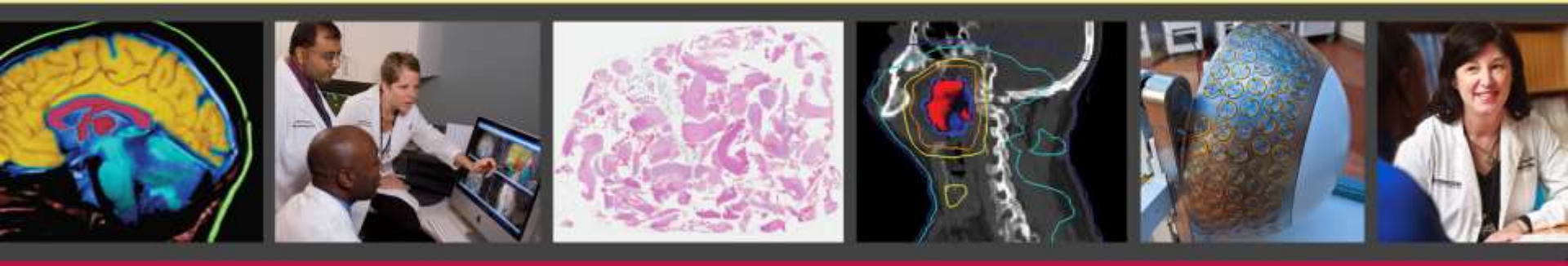

NRG Oncology Center for Innovation in Radiation Oncology (CIRO)

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Aims of CIRO

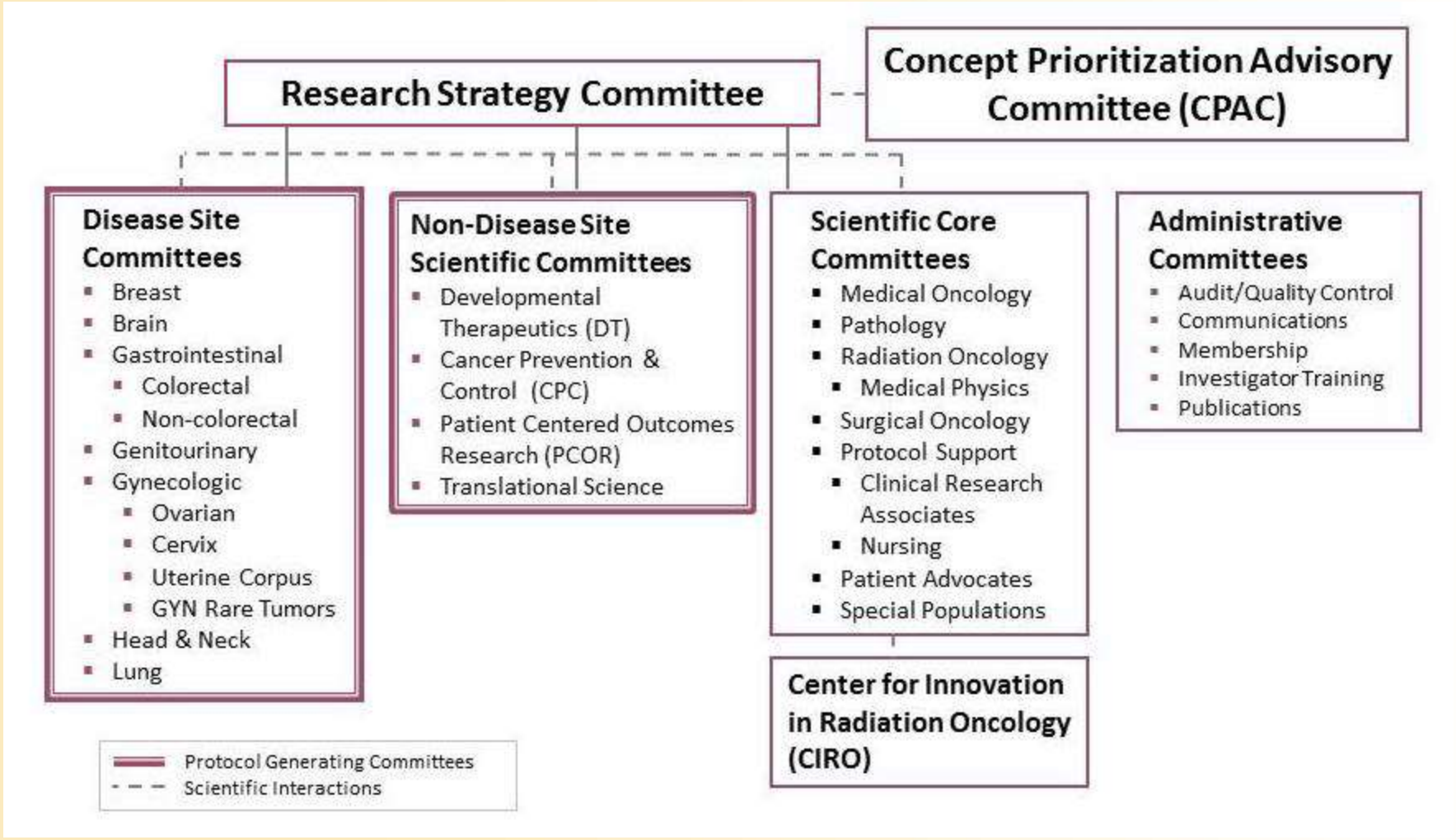
1) Promote innovative RT research within the entire NCTN

- Accelerate the testing of new radiation oncology innovations in NCTN clinical trials in all groups
- Facilitate the application of innovations across all appropriate protocols

2) Foster intergroup collaboration and protocol harmonization in terms of inclusion and description of RT techniques and delivery devices

- Reduce timelines for development of new protocols
- Improve the clarity of NCTN protocols

NRG Committee Structure



CIRO

1) Radiation Oncology Committee
2) Medical Physics Subcommittee
3) Staff
    - Medical Officer
    - Technical Officer
    - Support Staff
4) Statistical and Data Management Liaison

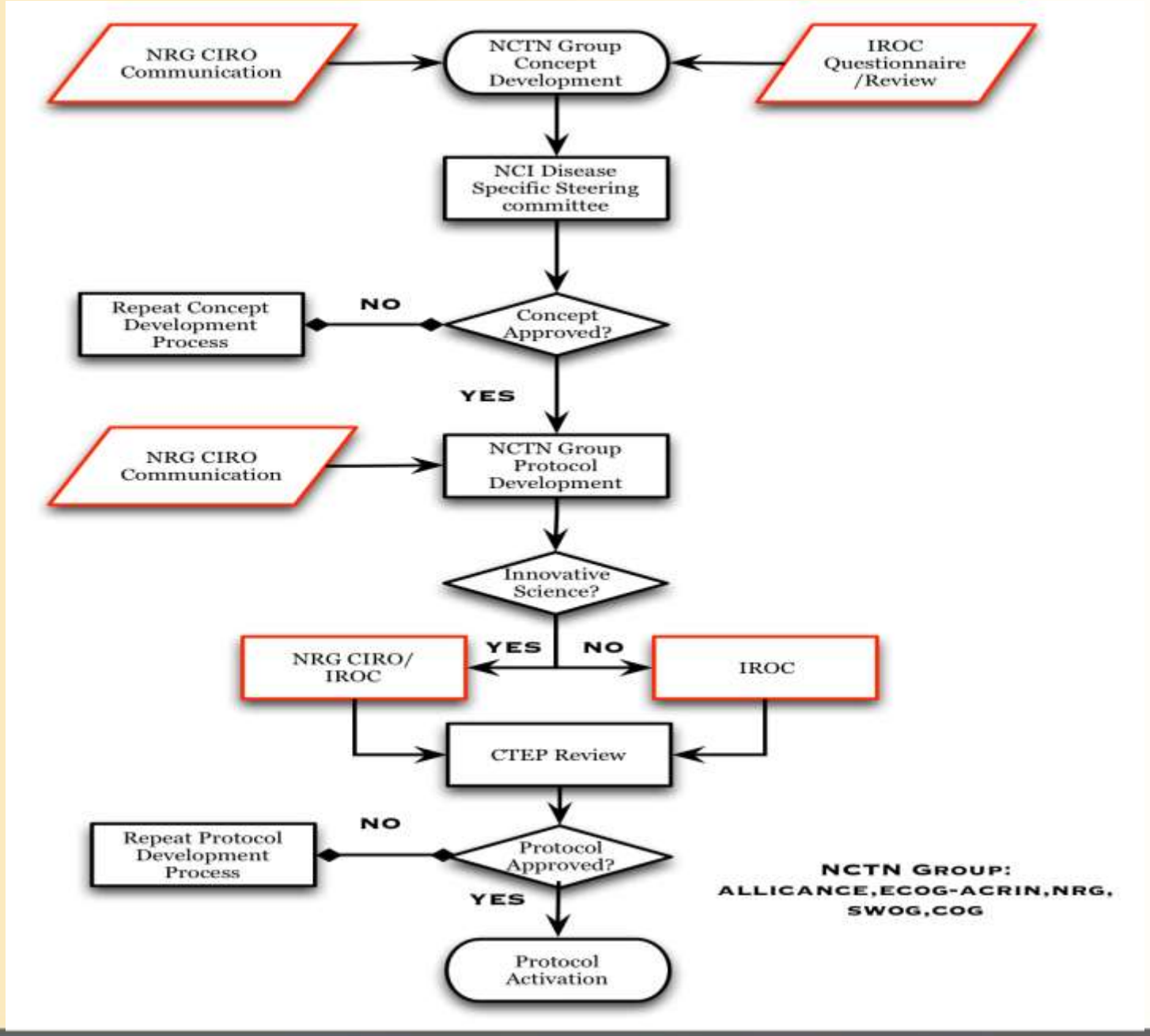
Medical Physics Committee Membership Structure

- Disease site liaisons
  - Leading member to report @ conference/meeting
- Intergroup, QA core liaisons
  - Leading member to report when requested
- Modality/technology liaisons (Working Group)
  - Leading member to report when requested
- Bio-informatics liaisons (WG)
- Industry liaison(s) (ad hoc guest)
- International liaison(s) (ad hoc guest)
- NCI and Staff liaison(s) (Data Manager, Protocol, Statistics) (invited talk on a rotating basis)

Professional Commitment

(Missions, Job Description)

- Interface with disease site committees as liaisons
  - Cover disease site conferences and face-to-face meetings
- Interface with intergroup, QA core and NCI
- Serve as Physicist PI on protocols
  - Overall protocol design and development
  - Specific responsibility for technical RT aspects and QA considerations
- General Responsibilities
  - Prospective identification of physics/QA objectives in new trials
  - Aid in creation of RT clinical Trials protocol templates
- Interface with Vendors of Technologies as needed
- Monthly conference
- Bi-annual NRG face-to-face meetings


NRG CIRO Communication
NCTN Group Concept Development
IROC Questionnaire /Review
NCI Disease Specific Steering committee
Repeat Concept Development Process
NO
Concept Approved?
YES
NRG CIRO Communication
NCTN Group Protocol Development
Innovative Science?
NRG CIRO/ IROC
YES
NO
IROC
CTEP Review
Repeat Protocol Development Process
NO
Protocol Approved?
YES
Protocol Activation
NCTN GROUP:
ALLICANCE,ECOG-ACRIN,NRG,
SWOG,COG

SDMC Collaborations

- Support design and implementation of innovative radiation oncology technologies
- Pursuit of innovative prospective designs to evaluate radiation therapy quality assurance (RTQA) as part of clinical trials
- Collaborate on predictive model building for radiotherapy and quality assurance

Quality Assurance Science and Vision

Adaptive QA;
Investigation into QA efficiency and efficacy;
collaboration with Imaging QA;
collaboration with NCTN group;

Future Quality Assurance

- Prospective QA trials, independently or as part of a clinical trial, with adaptive statistical design
- Retrospective QA data analysis for efficacy and efficiency

Thank You