CQIE PROGRAM
OVERVIEW

American College of Radiology
Clinical Research Center
This module is intended to provide a general overview of the CQIE program. All participants are urged to review the CQIE Manual of Procedures (MOP) for further details.

CQIE MOP and program information: www.acrin.org/NCI-CQIE.aspx

After you’ve reviewed this module please let us know by submitting the learning module attestation. The link is provided at the end of this module.
- Background of the CQIE program
- Roles & Responsibilities
- Site Initiation
- CQIE Methodology
- Qualification Requirements
- Data Submission / Analysis
CQIE

BACKGROUND
Advanced imaging plays a pivotal role in cancer care by providing the ability…

- To detect tumors early
- To guide therapy
- Disease monitoring/surveillance
Continued research and development of imaging agents, methodologies and technologies holds promise for better cancer care, for example...

- Improved tumor detection and characterization
- Research utility of and validate imaging biomarkers which may, in turn, provide for...
  - early “go” treatment decisions
  - confirmation of drug/treatment efficacy earlier
  - surrogate endpoints
There are often delays in conducting multicenter trials with advanced imaging aims due to...

- selection and qualification of sites to perform advanced imaging
- dissemination of relevant imaging standards
- Lack of coordinated collaboration among the imaging and treatment/research teams
The CQIE program was developed in response to a solicitation for proposals issued by SAIC-F, on behalf of the National Cancer Institute (NCI).

Primary objective: Establish a resource of ‘trial ready’ sites within the NCI Cancer Centers Program that are capable of conducting clinical trials with an integral molecular and functional advanced imaging endpoint.
What is CQIE?

- Qualify sites in the following quantitative imaging methodologies:
  - Volumetric CT (body), Volumetric MRI (brain)
  - DCE-MRI (body and brain)
  - Static and dynamic PET (body and brain)
- Provide imaging team with introduction to multicenter clinical trials
Roles & Responsibilities

National Cancer Institute:

- Committed funding to support CQIE development of qualification guidelines and the process to qualify cancer centers
- NCI will maintain oversight for the project
- Will serve as a liaison to the cancer center community
ACRIN:

- Develop and maintain qualification guidelines and associated SOPs
- Implement and administer qualification process (T0-T3)
- Maintain manual of procedures (MOP) to serve as a resource for participating cancer centers
ACRIN (cont’d):

- Collect and manage the images and data submitted by participating sites
- Perform the qualitative and quantitative analysis of submitted images
- Provide phantoms, on loan, as needed
- Administer (one-time) payment to sites upon successful T0 qualification
Sites:

- Agree to comply with qualification and QC guidelines
- Agree to participate for 4 years
- Identify on-site Project Leader to serve as the primary point of contact with ACRIN
Roles & Responsibilities

Sites (cont’d):

- Active participation and an ongoing commitment from all three imaging modalities - MR, CT and PET
  - Complete on-line learning modules
  - Baseline and annual phantom imaging
  - Clinical test cases (MR diffusion, PET)
  - Comply with set of standardized QC measures
SITE INITIATION
Site Initiation

- **Purpose**: To familiarize the site with CQIE qualification requirements and to provide assistance with technical issues associated with standardizing imaging acquisition protocols across multiple models, platforms, and software versions.
Site Initiation Options

- Two on-site initiation visits for each cancer center, to include phantom scan demonstrations.
  - one 1-2 day visit with CT & MR site teams
  - one 1 day visit with the PET site team

OR

- Modality-specific teleconferences
Site Initiation

- Two technologists from each of the three modalities should be identified for the site’s CQIE project team.
  - Complete 2 CQIE learning modules, the CQIE Overview and the modality-specific CQIE Procedures, prior to the site initiation visit.
  - Complete remaining modules within 6 months
  - Responsible for CQIE-related activities

- Review Manual of Procedures
- Set up (application download) of sFTP for image transmission
QUALIFICATION METHODOLOGY
In support of the primary objective, the CQIE program identifies benchmarks for quantitative imaging involving PET, DCE-MRI and CT/MR volumetric imaging. The CQIE qualification requirements are designed to...

- qualify scanners
- qualify site imaging capabilities
- promote imaging standardization / harmonization within multicenter clinical trials
Qualification Methodology

Needs of Quantitative Imaging

- Accuracy
- Reproducibility (across patients, time-points, instruments, hardware, software)
- Standardized Image Acquisition Protocols
Why standardize?

Standardization of imaging is essential for trials in which imaging plays a central role in the research aim / endpoint. Standardization helps control / limit the inter- and intra-variability inherent in multicenter imaging trials due to…

- multiple radiologists / image interpretation
- multiple technologists / image performance
- varying make/models of imaging equipment
- varying image quality
- varying image acquisition protocols
Qualification Methodology

Why qualify sites for imaging?
To determine site capability (personnel, skills, equipment) to perform trial imaging. For trials with quantitative imaging, qualification...

- is typically performed per trial, using trial-specific imaging guidelines, prior to patient accrual.
- can significantly slow study start up for the sponsor/CRO – need to develop imaging guidelines (no “industry-wide” standard), then identify, qualify, and train sites.
- This can significantly slow patient accrual - sites must “pass” qualification prior to enrolling patients.
QUALIFICATION REQUIREMENTS
Qualification Requirements

Components of CQIE qualification:

- Personnel qualification
- CQIE learning module
- Baseline & annual qualification imaging (phantom / test cases)
- Standardized QC
- Qualify site
- Qualify scanner
- Promote imaging standardization w/in multicenter trials
Personnel Qualifications

- Qualified and well trained personnel are central to producing high quality imaging studies and maintaining the scientific rigor required of multicenter quantitative imaging trials

  - Site attestation (MOU)— comply with minimum personnel qualifications as set forth in ACR Practice Guidelines and Technical Standards
CQIE Learning Modules

- CQIE Overview
- CQIE Procedures (CT) (MR) (PET)
- Introduction to Multicenter Imaging Trials
- Quantitative Imaging for Multicenter Trials (vCT) (MR) (PET)
Standardized Phantom Testing

- Same type of phantom, same tests - allows for a standardized evaluation of equipment performance and image quality characteristics.

- Phantoms provide an opportunity to evaluate site capability and compliance with specific imaging acquisition protocols.

- ACRIN will provide the CQIE-specified phantoms, on loan, to sites.
Standardized Quality Control

- QC is an important function of image quality and patient safety.
- QC of imaging equipment is fundamental to the goal of image/data standardization in imaging and therapy trials.
- CQIE establishes a set of QC measures to be performed across all participating sites.
Standardized Quality Control (cont’d)

- The QC measures were adopted by CQIE based on recommendations by organizations and researches involved in quantitative imaging.

- The QC measures should supplement current QC activities, not replace.

- Purpose is to help ensure the quantitative data generated is comparable within and across institutions, and over time.
## Qualification Requirements

<table>
<thead>
<tr>
<th>CQIE Summary of Qualification Procedures</th>
<th>Time Point</th>
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<tbody>
<tr>
<td></td>
<td>T0 Initial</td>
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<tr>
<td><strong>CT</strong></td>
<td></td>
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<tr>
<td>Learning Modules (at least 2 technologists)</td>
<td>X</td>
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<tr>
<td>Phantom Tests - ACR CT Phantom</td>
<td>X</td>
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<tr>
<td>Standardized Quality Control Tests</td>
<td>X</td>
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<tr>
<td><strong>MR</strong></td>
<td></td>
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<tr>
<td>Learning Modules (at least 2 technologists)</td>
<td>X</td>
</tr>
<tr>
<td>Test Cases - brain MR diffusion</td>
<td>X</td>
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<tr>
<td>Phantom Tests - ACR MRI Phantom</td>
<td>X</td>
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<tr>
<td>Phantom Tests - Body DCE-MRI Phantom</td>
<td>X</td>
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<tr>
<td>Standardized Quality Control Tests</td>
<td>X</td>
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<tr>
<td><strong>PET</strong></td>
<td></td>
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<tr>
<td>Learning Modules (at least 2 technologists)</td>
<td>X</td>
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<tr>
<td>Test Cases – 2 whole body, 2 brain</td>
<td>X</td>
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<tr>
<td>Phantom Tests - ACR PET Phantom</td>
<td>X</td>
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<tr>
<td>Phantom Tests – Uniform Cylinder</td>
<td>X</td>
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<tr>
<td>Standardized Quality Control Tests</td>
<td>X</td>
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DATA SUBMISSION & ANALYSIS
Data Submission

- All images must be submitted in DICOM format.
- Patient identifiers must be scrubbed from the test case images before they are submitted to ACRIN.
- Image data should be transmitted to ACRIN electronically via secure file transfer protocol (FTP).
- Download and installation instructions for FTP setup are provided in the CQIE MOP (appendix A-2).
- If necessary, sites can ship images to ACRIN on CD-ROM.
Phantom and test image data will be evaluated by the ACRIN Imaging Core Lab.

Analysis will include:

- Standard qualitative assessments, consistent with ACR practices.
- Additional qualitative and quantitative assessments performed at the ACRIN imaging core laboratory.
Evaluation Process:

- Submission-level QC review to determine if data set is complete and evaluable
  - **Pass** → image set tagged for analysis
  - **Fail** → ACRIN will contact the site for resolution

- Image data will be assessed per standard procedures based on modality-specific criteria and will receive a Pass or Fail score.
  - **Pass** → results report generated
  - **Fail** → ACRIN will contact the site for resolution
Sites will receive a summary report notifying them of their results and qualification status.

**NOTE:**

- Sites must receive a Pass score for all three of the modality testing to be CQIE-qualified. ACRIN will work with the on-site imaging team to resolve relevant imaging problems.
Qualification Summary

Initial qualification (T0)
- Application, Site Assessment Form, MOU
- Site Initiation Visit (on-site or teleconference)
- CT, MR, PET qualification imaging/data forms
- Implementation of standardized QC measures

Annual qualifications (T1-T3)
- CT, MR, PET qualification imaging/data forms
- Ongoing compliance with standardized QC
- Annual QC Questionnaire
Please follow the link below to report your review of this module
http://www.surveymonkey.com/s/85RB3T5

Questions should be directed to:
CQIE-Manager@acr.org
CQIE-MR-CT@acr.org
CQIE-PET@acr.org

Thank you!