Overview of the Certificate Course

Organizers: Michael McNitt-Gray, Jing Cai, Kristy Brock, Jihong Wang

Welcome to the Certificate Program!

This Certificate Course

- Suggested by Robert Jeraj of WGiTA (Imaging for Treatment Assessment Work Group)

- Tremendous helps from and coordination by HQ staffs

Clinical Trials

- Imaging Clinical Trials:
  - To determine the value of imaging procedures themselves for screening, detecting, diagnosing, guiding or monitoring treatment of disease (*e.g. digital mammo vs screen/film, others involves using combined MRI sequences to improve Dx accuracy*)

- Clinical Trials Using Imaging:
  - Imaging to evaluate the effectiveness of therapy/intervention trials (*detecting the changes of anatomical, functional, molecular, biomarkers using various MR imaging sequences*)

Clinical Trials Involve the Use of Imaging

MR Imaging studies can be used in a variety of clinical indications depending on the scientific aim and the specific needs of the trials including:

- Screening
- Diagnosis
- Staging
- As a prognostic or predictive biomarker
- Evaluation of response to treatment

Imaging based clinical trials

- Standardization of the various components in an imaging clinical trial is key and optimization is more critical!

- Important factors:
  - Imaging acquisition protocol
  - Imaging analysis hardware and software
  - Interpretation guidelines are much more important to imaging trials compared to therapeutic trials,
  - More critical when quantitative imaging analysis is involved.

- The promotion and assistance in the effort to create imaging standards and guidelines is one of the goals of the Cancer Imaging Program of the NIH, RSNA, ACR, ISMRM and many other organizations

Therapeutic based clinical trials

Less focus on the various components in the imaging chain but more on the overall consistency

Using imaging as biomarkers (or surrogate biomarkers): both anatomical and functional imaging

Consistency in imaging acquisition protocol, imaging analysis hardware and software, interpretation and measurement guidelines are also important, especially when quantitative imaging analysis is involved.

The promotion and assistance in the effort to create imaging biomarker standards is one of the goals of the Cancer Imaging Program of the NIH, RSNA, ACR, ISMRM and many other organizations

To ensure the quality of imaging biomarker

- Define well-established imaging biomarker
- Ensure consistency and equality at all sites
- Identical data acquisition for all sites, at all time
  - Including patient prep, positioning, protocol, reconstruction, QA
- Standardizes data analysis
- Ensure imaging data harmonization (data acquired on different imaging systems are comparable)

Imaging standardization

- Protocol design (Experts need to be involved from the beginning)
- Demonstrated necessary infrastructure by all sites
- Ability to collect high quality data (with phantom and patient data)
- Constantly monitored for incoming data
- Specific and detailed instruction for imaging data collection (e.g. patient positioned consistently, imaging slice collected all the same)
- Audited, and consistency checks

Main Tasks For Physicist Involved in Clinical Trials Using Imaging

- Depending on the specific aims and needs of MR imaging in the trials, there will be effort of the QA of MRI scanner system, optimization of imaging protocols/sequences, analysis software
- Establishing the QA and QC procedures using specific phantoms and associated analysis tools
- But, physicists can do more and play much more roles in the clinical trials, including trials in which physicist is the PI

Outline of this certificate course

7:30-9:30 Overview of Imaging's Role in Clinical Trial

- Overview of Imaging in Clinical Trials, Keyvan Farahani
- MRI Basics in Clinical Trial, Jihong Wang
- PET Basics in Clinical Trial, Timothy Turkington
- CT in Clinical Trials, Dianna Cody

10:15 -12:15 Recent Advancement of Imaging Guidance in Clinical Trial

- PET/MRI Update, Weili Lin
- MRI/Linac, Geoffrey Ibbott
- Adaptive Therapy/Hypofractionation, Feng-Ming (Spring) Kong
- Multi-Spectral CT, Shuai Leng
- QIBA/Imaging Analysis in Clinical Trials, Edward Jackson
- Radiomics/Big Data/Deep Learning in Clinical Trial, Laurence Edward Court

1:45-3:45 Current And Future Aspects Of Clinical Trials: Quality Assurance And Quantitative Imaging

- Proffered short talks
- Summary Q&A: Michael McNitt-Gray

4:30-6:00 The Roles and Task of Medical Physicists in Clinical Trial

- What Are the Roles and Task of Medical Physicists in Clinical Trial, Robert Jeraj
- Therapy Trials: RTOG and NRG, Ying Xiao
- ECOG-ACRIN Trials, Paul Kinahan
- RT Trials-Credentialing and QA, Fang-Fang Yin
- Wrap Up and QA, Michael McNitt-Gray