QIBA Q-CT Committee Weekly Update
Monday, July 12, 2010
11 AM CDT

Call Summary

In Attendance
Andrew Buckler, MS (co-chair)
P. David Mozley, MD (co-chair)
Harris Ahmad, MD
Maria Athelogou, PhD
Sung Chang, PhD
David A. Clunie, MBBS
Charles Fenimore, PhD
Gary Fullerton
David Gustafson, PhD
Sha He
Philip Judy, PhD
Michael McNitt-Gray, PhD
Daniel R. Nicolson
Kevin O'Donnell
Nicholas Petrick, PhD
Anthony P. Reeves, PhD
Yuanxin Rong, MD, MPH
Ganesh Saiprasad, PhD
Ann Scherzinger
Daniel C. Sullivan, MD
Hiro Yoshida, PhD
Binsheng Zhao, DSc

RSNA
Fiona Miller
Joe Koudelik

Group discussed existing activities and began defining next steps

- As additional resources come in, will need project management point-of-view and stages (of given tasks) in a formalized manner
- Tracking process needed
- Group outlined goals ("Aims") below:

End goals ("Aims"):

Process guidance with regulatory agencies inclusive of drug development and patient care
e.g., the ability to utilize data collected for qualification in device applications like 510(k)s and PMAs
Qualification (i.e., use in drug development use cases)
Briefing Document
Full data package
Device compliance (i.e., use in both drug dev and in individual patient management)
Compliance testing method and capabilities
Post-processing on standard data sets
Traceable phantom acquisitions

Template project steps:

Experimental Groundwork
Phantom
Characterize across acquisition setups (e.g., single-center phantom ala 1A)
Multi-center phantoms (e.g., 1C)
Meta-analysis / multi-algorithms (3A)
Clinical Data
Short-term reproducibility (e.g., coffee-break ala 1B)
Definition of clinical context and indications for use (e.g., "group 2")

Meta-analysis on retrospective analysis of data from prior trials ("3B")
Correlation with clinical outcome

Profiling
UPICT Protocol
QIBA Profile
Late stage lung
Neo-adjuvant lung

Open image archives, grouped by "acceptable", "target", "ideal" as defined in Profile
Phantom data
Data from FDA phantom acquisitions
Clinical data
Data request from pharma companies co-signed with PCF

Q-CT Group 3A

- Dr Athelogou agreed to lead new subgroup 3A
- Analysis of multiple phantom studies and algorithms based on existing meta-data
- Additional participation needed; all welcome to join; feedback welcome via email

Q-CT Group 3B

- Statistician to lead 3B; Dr Mozley to co-chair with pharma perspective
- Dr Kim to reach out to Dr Gatsonis for additional statistical support
- Retrospective data analysis based on meta-data from multiple trials
- Correlating with clinical outcomes a key issues, vs. comparing to RECIST

Q-CT Group 3C

- Profile (Prospective Clinical Studies)

Prospective vs. Retrospective Studies

- Need to minimize prospective studies by wisely using data already in-hand; need to shape ongoing studies; metadata analysis needs pharma data donations showing real value in individual clinical trials

Next Steps:

- Need to determine what statistical skills needed to lead group 3B
- Place projects into a project management process to help check progress
- Next call scheduled for: July 19, 2010 at 11 am CDT