Call Summary

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