QIBA Quantitative CT Committee
Monday, December 7, 2009
11 AM CDT

Call Summary

In attendance

Andrew Buckler, MS (co-chair)
Lawrence Schwartz, MD (co-chair)
Harris Ahmad, MD
Charles Fenimore, PhD
John Fraunberger
David Gustafson, PhD
Philip F. Judy, PhD
James Mulshine, MD
Kevin O'Donnell
Nicholas Petrick, PhD
Yuanxin Rong, MD, MPH
Daniel Sullivan, MD
Matthias Thorn, PhD
Hiro Yoshida, PhD

RSNA

Fiona Miller
Susan Anderson, MLS
Joe Koudelik

RSNA 2009

- QIBA kiosk and Committee posters were well-received and drew traffic; thanks to those who prepared posters and staffed the Meet- the- Expert sessions
- RSNA staff to follow-up with attendees who expressed interest in joining QIBA

Discussion of NEJM article (Dr Mulshine)

- NEJM article and accompanying editorial (Mulshine and Jablons) will be distributed to QIBA members; editorial mentions QIBA efforts
    - Volume CT for diagnosis of nodules found in lung-cancer screening. Mulshine JL, Jablons DM. N Engl J Med. 2009 Dec 3; 361(23):2281-2.
    - Management of lung nodules detected by volume CT scanning. van Klaveren RJ, Oudkerk M, Prokop M et al. N Engl J Med. 2009 Dec 3; 361(23):2221-9.
- Van Klaveren et al study used multidetector computed tomography (CT) in lung-cancer screening trials involving subjects with an increased risk of lung cancer; participants underwent CT screening in years 1, 2, and 4 of a randomized trial of lung-cancer screening.
    - Compelling example of lung cancer diagnostic quantitative imaging; its generalizability to be determined
- Suggestion to visualize Committee workplan in 4 Profiles; the clinical relevance and technical considerations will have similarities (diagnosis v. therapy) and differences (the measurement science)
    - *Diagnostic*: 1) asymptomatic screening (may be lower dose) and 2) symptomatic stratification and
    - *Therapeutic*: 3) neoadjuvant or other early stage and 4) later stage cancers

Discussion of neoadjuvant widow of opportunity Profile (Dr Mulshine)

- The window of opportunity Profile will be more research than therapeutic
    - Involves expression profiling (by molecular testing) to determine whether target is modified by drug exposure in short time period (2-3 weeks) before surgical intervention
    - Will want to intersect efforts with phantom work; acquisition protocols will provide a sound start
    - Profile may generate small but high quality data sets on prototyping certain approaches, e.g. screening vs. therapeutic settings
    - Begin by setting out how techniques may vary (e.g. range of possibilities), then converge like areas
    - Additional baseline scans deemed appropriate for this high-risk group

- Forthcoming article will review Milan cohort with ground-glass opacities and placebo vs. aerosolized steroid for chemoprevention

Roadmap and engagement with FDA (Mr Buckler)

- Roadmap activities designed to address stakeholders and regulatory needs of FDA
- PhRMA Imaging Group (PIG) chaired by Dr Mozley is advocating the use of vCT as an imaging biomarker as a replacement for RECIST
- PIG is discussing communication with FDA CDER via a paper or a Special Protocol Assessment (SPA) meeting to seek feedback on steps needed to qualify vCT as a surrogate endpoint
- The ultimate goal is to validate vCT as primary measure for numerous applications; no "truth" for vCT measurements yet
- Mr Buckler compared two documents, 1) Dr Mozley/PIG outline for SPA meeting and 2) QIBA Roadmap from NIBIB proposal
- Using the QIBA Roadmap document, Mr Buckler outlined a workplan to focus efforts, mark progress and provide a project management foundation
- Proposed was a SPA for both vCT and FDG-PET; no SPA currently scheduled but the tie-in with the Roadmap needs to be addressed
- External drivers include optimization of performance of imaging biomarkers and their qualification as surrogate endpoints: how work is organized will depend on the "customer"
- As an example:
    - 'Technical Characteristics and Standards' section resembles an assay validation (CDRH focus)
    - 'Clinical Performance Groundwork' section may elucidate endpoint qualification for drug trials like a SPA (CDER focus)
    - 'Clinical Efficacy Groundwork' section may drive scientific and financial incentives (CMMS focus for use in establishing reimbursement for individual patient management, FDA's Critical Path Initiative motivates clinical trial use)
- Rather than dichotomizing, an overview on all topics may be relevant to both CDER and CDRH

Next Steps

- Mr O'Donnell to post draft neoadjuvant window of opportunity Profile on wiki
- Dr Mulshine to suggest wording for Executive Summary section of Profile
- Committee to develop workplan for 2010: 4 lung cancer Profiles; 2 pulmonary (emphysema and asthma) Profiles and continue Roadmap discussion