QIBA VolCT Update WebEx Monday, March 2, 2009 11AM (CST)

Call Summary

In attendance:

Andrew Buckler, MS (Co-Chair)
David Mozley, MD (Co-Chair)
Maria Athelogou, PhD
Rick Avila, MS
Ekta Dharaiya, MS
Charles Fenimore, PhD
Robert Ford, MD
Michael McNitt-Gray, PhD

James Mulshine, MD Kevin O'Donnell Nicholas Petrick, PhD

RSNA

Susan Anderson Joe Koudelik

Introduction and agenda (Mr. Buckler)

Goal is to continue to review Profile Claims and Details on Wiki

Claim language (Mr. Buckler)

- Mr. Buckler and Mr. Avila refining a table for "expectation setting" with a convergence of:
 - Top down: requirement or user needs viewed as an improvement in analytical power per subject from RECIST baseline
 - o Bottom up: what can be achieved/what is possible for relevant configurations, e.g., different slice thicknesses and/or different algorithm types
 - o "Analytical" Groundwork to support what can be achieved (augmenting the experimental Groundwork of our validation plan)
- Table is designed in a tolerance stack-up manner
 - o Rows: successively challenging contributions to errors
 - Base case: step edge tumors with anisotropic spatial sampling limited by slice thickness
 - Boundary error under ideal conditions, PSF limited
 - Including typical vascular attachment and bronchial airways
 - Including pleural attachment
 - Non-solid tumors
 - Columns: to capture performance differences based on slice thickness and/or type of algorithms
- More interaction needed with users to iterate expectations based on early and late profiles
- Group will review as results available

Review of Details

Protocol and profile relationship

• Clinical trial protocol will specify what Profile to use

Activity: Patient Preparation

- Question of whether to be more or less specific--does this section provide enough detail?
 - o Include breath-hold?
 - Measurement made under constant contrast conditions
- Argument to make section stronger in interest of "standardizing human behavior"
- Discussion of whether to:
 - 1. Be prescriptive: specify items such as injection rate/delivery time/total amount/contrast agent or
 - 2. Use as placeholder for "same way every time" or "according to current practice in local institution" or
 - 3. Link to best practice/standard of care. Avoid being too prescriptive; state "example of best practice/standard of care is <u>insert link</u> or "do as needed but insure that details are recorded"
 - 4. Recording of parameters in profile. Use "shall" language, e.g. Site staff shall record how _____" and use controlled list of options

Activity: Image Acquisition

- Discussion of use of ACRIN 6678 and NLST protocols' acquisition parameters
 - Open to suggestions of other useful protocols
- Specify method or point to resources to use to achieve certain results?
- Because NLST is a screening protocol, ACRIN 6678 may match our needs more closely
- Reminder that many other Profiles are needed, e.g. angiogenesis signature; we are developing *template* based on claims for late stage lung cancers in large clinical trials
- Explore NLST protocol left column with parameters of *detector*, *width*, *table speed*, *scan time*, *scanner model*, etc.
 - o Stay flexible; parameter lists may change as scanners change
- Use NLST as format?
 - o Initialize with actual values
 - Move beyond stated values
- Eventual tie-in, or nest with UPICT template
- ACRIN 6678 and NLST chose range of values; this group to decide on which elements need specific values
 - o Single values
 - o Range of values
 - Unconstrained values

Next steps

- Activity: Patient Preparation: Dr Mulshine will review section on positioning
- Activity: Patient Preparation: Contrast Administration needs to be fleshed out
- *Activity: Image Acquisition*: Mr O'Donnell to draft each parameter from protocols on a different line for discussion
- Claims table (Mr Buckler and Avila) for discussion
- Continue review of Activity: Image Acquisition
- Continue to think through parameter elements (not simply values) -- Dr. Petrick to provide some examples