In attendance:

Andrew Buckler, MS (Co-Chair)  James Mulshine, MD  
David Mozley, MD (Co-Chair)   Kevin O’Donnell  
Maria Athelogou, PhD          Nicholas Petrick, PhD  
Rick Avila, MS                
Ekta Dharaiya, MS             RSNA  
Charles Fenimore, PhD         Susan Anderson  
Robert Ford, MD               Joe Koudelik  
Michael McNitt-Gray, PhD      

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
  - Bottom up: what can be achieved/what is possible for relevant configurations, e.g., different slice thicknesses and/or different algorithm types
  - “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
  - 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?
  - 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 [insert link] 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.
  - Stay flexible; parameter lists may change as scanners change
- Use NLST as format?
  - 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
  - Single values
  - 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