QIBA CT Volumetry Biomarker Committee (TC) Update Call

15 December 2014 at 11 AM CT

Call Summary

In attendance:

Samuel G. Armato, III, PhD (Co-Chair)
Gregory V. Goldmacher, MD, PhD, (Co-Chair)
Maria Athelogou, PhD
Hubert Beaumont, PhD
Andrew Buckler, MS
Charles Fenimore, PhD
David Gustafson, PhD
Rudresh Jarecha, MBBS
Philip F. Judy, PhD
Hyun Grace Kim, PhD
James Mulshine, MD
Nancy Obuchowski, PhD
Adele Peskin, PhD
Nicholas Petrick, PhD
Ehsan Samei, PhD
Doug Steinfeld
Daniel Sullivan, MD
Ying Tang, PhD
Luduan Zhang, PhD
Binsheng Zhao, DSc

RSNA:
Joe Koudelik
Julie Lisiecki

Agenda: Future planning and Field Test Discussion

Discussion:

- Steps needed to complete the Profile and achieve Field Test / Technically Confirmed Status:
  - Public Comments to be resolved
    - Drs. Goldmacher and Petrick and Mr. O'Donnell are working to resolve public comments with a goal of completion by the end of January 2015
    - A draft for biomarker committee review will be circulated
  - Drs. Armato and Siegelman are working on extracting a compliance checklist from the Profile for an "at-a-glance" reference
  - Once these steps are complete, the next phase will be the field test
    - Drs. Gillies and Siegelman have volunteered to be initial testers of Profile implementation
  - Prior to implementing a field test, the Profile must be reviewed for the following:
    - Is the Profile comprehendible in a real-world setting by a technologist?
    - Are quantitative claims valid?
    - Can a field test be done in parallel with Profile development?
      - Defining the "nature" of the Field Test is critical, e.g. what will input data look like, what will the output measurement/metric be, etc.
      - A virtual lab/ platform with multiple readers and multiple labs was proposed as an option for consideration.
      - This would be related to an infrastructure for comparing algorithms
      - Prior to launching such a system, some studies need to be done to tease out variance
      - Breaking the claim into manageable components to validate separate portions and later bringing them back together for summation of the claim may be the only viable option
      - Short of a large clinical trial, consideration must be given to what can be done in the interim
        - Repeatability parameters are still needed
        - Ethical issues regarding patient management must be considered
        - The Profile must be validated in a real-world setting
      - Consideration to be given to piggy-backing a test of the Profile onto an existing clinical trial through partner organizations

Action items: Mr. Buckler to summarize future directions for discussion at the next Biomarker Committee meeting

Next Call: January 5th *or* January 12th – Next call for the CT Volumetry Biomarker Committee (?) – Co-Chairs to confirm.