QIBA CT Volumetry Biomarker Ctte (BC) Call

11 July 2016 at 11 AM CT

Call Summary

Additional notes provided by Mr. O'Donnell

| In attendance: | | | RSNA: |
|---|------------------------|-----------------------|----------------|
| Gregory Goldmacher, MD, PhD, MBA (Co-Chair) | Vadivel Devaraju, PhD | Kevin O'Donnell, MASc | Joe Koudelik |
| Ehsan Samei, PhD (Co-Chair) | David Gustafson, PhD | Eric Perlman, MD | Julie Lisiecki |
| Jenifer Siegelman, MD, MPH (Co-Chair) | Lubomir Hadjiiski, PhD | Nicholas Petrick, PhD | |
| Maria Athelogou, PhD | Edward Jackson, PhD | Aria Pezeshk, PhD | |
| Hubert Beaumont, PhD | Rudresh Jarecha, MBBS | Ying Tang, PhD | |
| Andrew Buckler, MS | Claudia Kirsch, MD | Luduan Zhang, PhD | |
| Heang-Ping Chan, PhD | Nancy Obuchowski, PhD | | |

Summary of Remaining Open Issues for the CT Tumor Volume Change for Advanced Disease (CTV-AD) Profile:

- *Profile scope:* Since the Committee would like to promote the Profile for use on tumors throughout the chest, abdomen and pelvis, the Profile title and scope have always been kept non-anatomy-specific.
- Claims scope: Since the Profile is not anatomy-specific, a decision needs to be made regarding the scope of the claims
 - Supporting data for the current Claims is based on the RIDER (lung-specific) dataset
 - Alternative A: Keep the existing claims (that the performance values are valid for all tumors) and add a
 disclaimer that performance was calculated from lung data only, but BC experts anticipate that
 performance in the liver, lymph will meet or exceed the performance in lung.
 - Alternative B: Add the word "lung" to the current claims and add a paragraph explaining that claims for liver, lymph, etc. will be added when data is available, but in the meantime the committee still recommends use of the Profile as best practice for liver, lymph, etc.
- Subject matter experts (SMEs) provided guidance that the BC can safely assume that segmentation / volumetry in the liver, lymph, etc. will have the same repeatability and bias as that in the lung
- The committee decided to go with Alternative A to publish the Publicly Reviewed (Consensus Profile).
- Mr. O'Donnell will draft the additional paragraph.

Action items (CT Tumor Volume Change for Advanced Disease (CTV-AD) Profile):

*as provided by Dr. Goldmacher

- Location of test-retest dataset
 - o QIDW vs TCIA
 - o Link path: TBD
 - o Ad hoc call with Dr. Erickson, Dr. Jackson, Mr. Buckler, and a CT Volumetry BC co-chair
- Dr. Petrick location of the FDA Lungman N1 data
 - Establish QIDW location
 - Collate and upload
 - o ~1 week
- Dr. Obuchowski and Mr. Buckler reference for repeatability requirement numbers (16%, 21%)
 - o Mr. Buckler will send to Mr. O'Donnell (done)
 - ~1 week to incorporate
- Noise/res information (Dr. Petrick / Dr. Samei / Dr. Siegelman)
 - GE Dr. Samei f50 and Noise SD values from the Duke Database for GE Lightspeed 16 @ 1.25mm and sharp kernel, and the vCT 64; Dr. Samei will send table to Mr. O'Donnell by COB 7/11
 - Siemens Dr. Petrick to send Dr. Samei model and protocol information by end of 7/15
 - o Philips
- .CSV file similar with the coordinates of the 7 lesions to measure

- o Dr. Samei to send Dr. Petrick CSV file by COB 7/11/16
- o Dr. Petrick to compose equivalent by 7/15
- RSNA Staff list of profile contributors for Appendix A
 - o Update once additional respondents are compiled

Next Call: Monday, August 8th at 11 am CT | Profile review | Next steps