QIBA CT Angiography Biomarker Committee (BC) Call
28 January 2019 at 11 AM CT
Call Summary

On Call			**RSNA Staff**
Andrew Buckler, MS (Co-Chair)	Philipp Hoelzer, PhD	Raquel Themudo, MD, PhD	Fiona Miller
Uwe Joseph Schoepf, MD (Co-Chair)	Nancy Obuchowski, PhD	Marly van Assen, MSc	Joe Koudelik
Kevin DeMarco, MD	Taylor Richards, PhD	Akos Varga-Szemes, MD, PhD	Julie Lisiecki
Svetlana Egorova, MD, PhD			

Moderator: Andrew Buckler, MS

Remaining Sections for Profile Discussed:

- All sections except claims have been written
- Protocols within the Profile are nearly ready for public comment
- Some action items remain before the Profile can be considered complete, including the following:
    - Finalization of specific wording for the claims
    - Placement of the dose table within the Profile initiated by Dr. van Beek
        - Association with individual scanners?
        - Placement in the reconstruction section?
        - Placement in the assessment procedures for scanners?
        - Drs. Van Beek, Taylor and Samei to confirm proper placement in Section 3

- Details regarding claim terminology were discussed:
    - Types of claims: cross-sectional (single encounter/time-point) vs. longitudinal (multiple encounters/time-points)
    - Claims are made on the basis of certain data:
        - Statistical performance metrics
        - Methodology used to select appropriate metrics and how to assess them
        - Performance methodology
        - Use of definitions in a specific way, e.g., suggestion to refer to QIBA Metrology Papers

- The BC has the benefit of data pertaining to
    - Bias of anatomic structure from phantoms
    - Bias of tissue characterization from histology
    - intra- and inter- reader data for both structure and tissue type from clinical data sets

- Claim language is constrained due to the lack of available clinical test-retest data.
    - All committee members encouraged to provide additional test-retest data or identify sources

- The two types of clinical data we have will be used for the claims in the first version of the Profile:
    - Bias data
    - Reader variability

- Dr. Obuchowski made the following suggestions to articulate the claims:
    - Use a technical performance claim based on bias and reproducibility
    - Generalize the information for the biomarker, specifying details for bias and reproducibility
    - Note that measurands do not have a bias, but bias may exist in measurements of the measurands Test-retest variability may be used when it is available to strengthen the claims further.
    - Explanations of these details and references will need to be included in the Profile
        - Terms are needed that are statistically correct but also easily understood by non-statisticians
        - Statistical terms will be explained in greater detail in the discussion section
    - There was additional discussion regarding variability when using semi-automated analysis software (algorithms), as well as the differences between readers utilizing their own judgment
    - Mr. Buckler shared some examples of how algorithm differences were addressed in another Profile

- Emphasis was placed on providing user guidance in a manner that does not restrict vendor innovation

Action items and Next Steps:
- Dr. Obuchowski and Mr. Buckler to draft a claim and format the bias table for the next call, 2/11
- Procuring test-retest data
    - Dr. Lal and Mr. Chrencik may have data that could be shared for the Profile development: they have a carotid dataset with some number of subjects with 2 encounters collected within a week or so; which could provide the first test-retest dataset for Profile development
    - Additional test-retest data are welcome
        - Groups of 16 – 32 patients have been used in the past for similar tests
        - Some of this data will also be useful in the future for conformance testing
- Working toward releasing for public comment once claims are finalized
- Seeking volunteers for the feasibility test where the Profile will be tested in real-world conditions to see if the requirements can be met
    - 2 – 4 volunteer academic sites are needed for the feasibility test

Next call: Monday, February 11th at 11 am CT

QIBA Wiki CT Angiography BC page: http://qibawiki.rsna.org/index.php/CT_Angiography_Biomarker_Ctte