### QIBA Multi-parametric Metrology TF Call

09 December 2020 at 10:00 AM CT Call Summary

In attendance RSNA

Andrew Buckler, MS Charles Hatt, PhD Daniel Sullivan, MD Joe Koudelik Jana Delfino, PhD Bernice Hoppel, PhD Ying Tang, PhD Julie Lisiecki Nandita deSouza, MD Erich Huang, PhD Xiaofeng Wang, PhD

Alexander Guimaraes, MD, PhD

Moderator: Dr. Delfino

# **Approval of Call Summary**

• The notes from November 23, 2020 were approved as presented

## **Use case #2**: (Dr. Delfino) – Topics discussed included:

- Dr. Delfino led a brief discussion on phenotype analysis for which there is no ground truth
- Her view is that these types of exploratory studies for which the objective is to identify groupings of patients
  with similar characteristics, would not fall within the scope of Use Case #2, where the objective is to provide
  correlation/agreement with a clinically established phenotype.
- The group agreed that they are using the term "phenotype" to mean "an objectively measured or described characteristic based upon something other than radiological imaging (e.g., histopathology or genomic expression)."
- Mr. Buckler led the Use Case #2 discussion by walking the group through a cardiac example for atherosclerosis, covering the following topics:
  - Clinical Context
  - What type of biomarker it is, using the FDA-NIH Biomarkers, EndpointS, and other Tools, or "<u>BEST</u>" definition
  - Plaque Type system (and the depth of its scholarship)
  - Form of target "claim"
  - Approaches that could be taken
  - Approach taken by vascuCAP (with validation plan)
  - o Current results
- The difference between diagnostic and monitoring biomarkers was discussed, along with a likely surrogate endpoint
- The plaque type system was carefully and intentionally chosen to evaluate technical performance only, to avoid the obligation for clinical validation

Next call: Use case #3 (Dr. Huang) on Monday, Dec. 21st at 2 pm CT

#### Call Schedule: Presenters: please review.

| Date:                        | Topic:                                   | Lead:      |
|------------------------------|------------------------------------------|------------|
| Monday, Dec 21 (2 pm CT)     | Use case 3: Risk prediction              | Dr. Huang  |
| Monday, Jan 4 (2 pm CT)      | Use case 4: Radiomics                    | Dr. Wang   |
| Wednesday, Jan 20 (10 am CT) | Use case 1: Multi-dimensional descriptor | Dr. Raunig |

#### Use cases:

- Use case 1: (Multi-dimensional descriptor) a panel to determine how to care for a patient
- Use case 2: (Phenotype classification) rule or decision tool to diagnose phenotype
- Use case 3: (Risk prediction) several biomarkers will be evaluated to create a prediction or risk score
- Use case 4: (Radiomics) may not have a specific biomarker for reference