

## QIBA Multi-parametric Metrology Call

09 March 2020 at 2 PM CT

Call Summary

### In attendance

Nancy Obuchowski, PhD (Co-Chair)

Huiman Barnhart, PhD

Michael Boss, PhD

Jana Delfino, PhD

Nandita deSouza, MD

Timothy Hall, PhD

Erich Huang, PhD

Rudresh Jarecha, MBBS, DMRE, DNB

Marina Kondratovich, PhD

David Raunig, PhD

Daniel Sullivan, MD

Xiaofeng Wang, PhD

### RSNA

Joe Koudelik

Julie Lisiecki

**Moderator:** Dr. Obuchowski

### FDA Evaluation of New Devices Presentation:

- Dr. Kondratovich provide an overview and shared slides on risk prediction from the FDA experience
- These slides have been distributed to the Multi-parametric listserv for reference
- Dr. Kondratovich to send additional information regarding FDA/CDRH process guidance for scoring devices
- She suggested using the In Vitro Diagnostic Multivariate Index Assay (IVDMIA) as a starting point for the discussion of risk prediction
  - This tool is defined as a device that: “combines the values of *multiple* variables using an interpretation function to yield a *single*, patient-specific result or score that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.”
- She also recommended the Monte Carlo simulation of error propagation to aid with determining precision
- Dr. Huang will moderate the next call with his presentation on risk prediction, which will be held on Wednesday, March 25<sup>th</sup> at 10 am CT

### Call Schedule:

Date:	Topic:	Lead:
Wednesday, March 25 (10 am CT)	<b>Use case 3:</b> Risk prediction	Dr. Huang
Monday, April 6 (2 pm CT)	<b>Use case 4:</b> Radiomics	Dr. Wang

### 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

### Announcements:

- Dr. Delfino mentioned that all FDA workshops and public meetings are cancelled for the month of March (this was based on a general FDA announcement; no further specifics were available)

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