

## **QIBA COPD/Asthma Committee**

Tuesday, February 2, 2010  
11 AM CST

### Call Summary

#### **In attendance**

Philip Judy, PhD (Co-chair)  
Andrew Buckler, MS  
Zachary Levine, PhD  
Michael McNitt-Gray, PhD

#### **RSNA**

Fiona Miller  
Susan Anderson, MLS  
Joe Koudelik

#### **Status of COPDGene CT Number Accuracy Conference**

- Dr Crapo has postponed planning for large mtg with vendors; instead will convene smaller group meeting of COPDGene investigators, ctte members and others to move towards consensus before involving vendors
- The COPD Profile can help focus activities and frame 'wish list' of vendors in a positive manner

#### **Ancillary Study design for committee (Dr Judy and Mr Buckler)**

- The ancillary study plan is part optimization, part characterization
- Outlines activities which include:
  - Background data: snapshot of where we are with literature search and other components
  - Acquire or develop phantom:
    - Intermediate goal: modifying COPDGene phantom to mimic air trachea
    - Characterize variability as Q-CT Dr Fenimore and Group 1C is doing
- "Challenge problem" is defined as making improvements; proprietary platform-dependent solutions guided/standardized by platform-independent solutions
  - The supposition is that engineering or software changes are necessary to achieve desired performance
  - Manufacturers appear willing to cooperate with scanning and setting within current design but concern about their interest in moving from current design to new design to meet external 'challenges'
    - Benefit to vendors who meet compliance certification is improved product which meets demand Profile-compliant product
- Workplan will demonstrate convincingly to vendors that pulmonologists and radiologists' suggestions are do-able
- Vendor product lines to be 'Profile compliant', where 'compliance' is a product feature leading to increased product utilization (based on features)
- Positive feedback on better definition of HU; Dr Levine to pursue
- Discussion of streaking on high-contrast features; another iteration of phantom with patterns of high-contrast objects may be helpful to mimic noise and shift HU values
- Discussion of funding or pursuing workplan with volunteers

#### **Phantom modification**

- Want to avoid work or modifications which have been addressed with ACR phantom; need to determine if the ACR phantom mimics the air trachea issues

- Dr McNitt-Gray discussed loan of ACR phantom, which has air circle in relatively solid disk, to Dr Judy; Dr Judy has experience with linearity phantom from Kyoto company which has similar features

**FDA Guidance for Industry - Chronic Obstructive Pulmonary Disease: Developing Drugs for Treatment (Draft Nov 2007)**

- Group will consider whether Nov 07 draft and any updates have recommended/approved primary and secondary endpoints
- Dr McNitt-Gray will share document with colleagues for comment
- Are select CT measurements approved as primary or secondary endpoints? Do sponsors want this?

**Next Steps:**

- Dr McNitt-Gray to distribute Draft FDA *Guidance for Industry - Chronic Obstructive Pulmonary Disease: Developing Drugs for Treatment* to colleagues for comment
- Dr Judy welcomes guideline feedback
- Next call scheduled for Feb 16, 2010 at 11 AM CST