

QIBA COPD/Asthma Committee Update Call

Tuesday, September 29, 2009

11 AM CDT

Call Summary

In attendance:

Philip Judy, PhD (Moderator)
James Crapo, MD
Sean Fain, PhD
David Jurado
Zachary Levine, PhD
David Lynch, MD
Michael McNitt-Gray, PhD

Daniel Sullivan, MD
George Washko, MD

RSNA
Susan Anderson, MLS
Joe Koudelik

Overview of QIBA (Dr Sullivan)

QIBA was formed to bring together various stakeholders from academia, industry, government, associations and CROs with a modality and/or disease focus on imaging biomarker development. QIBA's goal is to identify key sources of accuracy and reproducibility and develop strategies to mitigate sources of error. The primary focus is clinical trials initially, with clinical practice eventually.

Purpose of QIBA COPD/Asthma Committee

- To develop a Target Profile (Ideal/Target/Acceptable)
- To define and complete necessary groundwork, e.g. where things stand now
- Determine what is needed to achieve Profile Claims
- Dr Hoffman of Iowa has COPDGene phantom scans from COPDGene sites. These scans are done for the QA program. The phantom contains water, acrylic, and lung foam.
- Determine what guidelines device manufacturers should follow to demonstrate compliance
 - Develop compliance process with manufacturers' input
 - Reasonable/feasible from the medical physicists and financial point-of-view
- VolCT Tech Committee pursuing a similar path, i.e. enticing vendor engagement
- Provide vendors with Ideal, Target, Acceptable targets for precision and accuracy achievement
- Manufacturer Compliance
 - Need to know how to check manufacturer compliance
 - What phantoms are to be used in compliance testing?
 - Metrics need to be determined; need a technically reproducible measure at a non-disease level of effect

General Process

- Develop Profile
 - Document describing all QIBA goals, based on Performance Claims
- Performance Claims
 - Statements on how imaging biomarkers are to be used in clinical trials and practice as well as how to achieve Claims
- Much preliminary work already done by COPDGene efforts
- COPDGene study remains the main focus

- Pharmaceutical companies need quantitation for CT scans as well
- What Claims should QIBA COPD/Asthma Committee make?
 - Claims concerning precisions and accuracy needed
 - What numbers are reasonable?
 - Levels of Claims needed
- How precise can we measure under best research conditions?
 - e.g. Precision needed to measure a 2mm wall thickness?
 - Phantom work needed to establish these values
- Reference datasets useful for reproducibility tests
- CODP Gene phantom has already produced estimates of reproducibility but it has limited features
- Need more variation of sphere sizes and contrasts in phantom
- Coffee Break experiment results used by the Vol-CT Tech Ctte could be useful leading to a synergy between committees

COPD Morphology Matrix Overview (Dr Lynch)

- Morphology matrix is to identify the 2-3 most important issues to move the field forward
- Technology, patient related issues, and morphology have been separated in current matrix
- Current challenge to airway morphology evaluations is space resolution, e.g. limited pixels due to processor issues
- Normal variance within and between patients not known or understood
- Largest challenge to COPD
 - Spatial resolution issues; accurate measurements are difficult to make, e.g. CT will always overestimate
 - What is acceptable CT overestimating?
 - Lack of knowledge of normal v. abnormal concerning patient variance
 - Lack of validation; need to develop metrics to validate
- Need to determine clinical relevance if these measurements
 - Difficult to determine what measurements are important with COPD

Need to collect data and correlate to prove any hypothesis to clinical relevance; this may be 3+ years away

This committee needs to develop resolution parameters (metrics) and work with the clinical community to subdivide COPD into clinical subtypes, e.g. airway wall thickening

- For discussion:
 - What might be reasonable Claims to begin with?
 - What kind of phantom to use and data to collect?

Reference Standard Phantom

- SNR limited in airway measurements; how much impact does SNR have in COPD measurements?
- Effects of slice thickness across scanners; how does this affect small area measurements?
- Number of evaluation methods to define airway wall thickness; impact of normalization process on measurements also needed
- Does the Eclipse Phantom meet our needs? Existing phantom does address numerous issues
 - Seven separate internal sections including an “air section”
 - Water fill material used with acrylic foam of various densities
 - Expensive phantom at \$5K
- CODP Gene phantom contains fewer internal structures, but more oblique variation

- Simple and inexpensive
- Clinical setting require simple protocols, thus oblique features needed
- Perhaps two phantoms needed
 - QA phantom for multi-site used (simple design)
 - Eclipse-like phantom for physics issues (complex design)

Phantom Fill Material Density

- Need fill material to assist the development of internal standards on actual patient scans and air trachea CT numbers dealing with inconsistency between scanners
 - e.g. Claim is that CT scanners need to be consistent within 1% of density measurements, for example, 1-10 HU units
- By improving the density measurements to 1% HU, clinical studies can decrease subject numbers and decrease trial timeframe
- A strawman would be reasonable to pursue
- Defining what is acceptable as standard to be a future goal
- COPD/Asthma Committee to increase accuracy across centers, leading to study designs based on few patients (e.g. 100 patients)
- CT manufacturer participation also needed

Follow-up to the COPDGene 2009 meeting proposed

- RSNA to consider sponsorship and facilitation of proposed f2f meeting in 5-6 months (Spring 2010) with vendor involvement
- Drs Sullivan and Crapo to discuss coordination
- Tap into COPD contacts (i.e. key people)
- Groundwork and reliability data needed leading up to the meeting
- Need to converge on Claims language and supportive groundwork
- What phantom data has been obtained/what is still needed?
 - Consider including these groups:
 - Imaging cores
 - Iowa?
 - ICCG (?)
 - National Jewish Health
 - Brigham and Women's
 - Manufacturers:
 - R Mather – Toshiba attended
 - Philips attended
 - P Licato – GE attended
 - Siemens attended
- Dr Crapo to circulate participant list from Feb '09 COPDGene f2f

ACRIN 2009 Meeting

- A f2f of QIBA COPD/Asthma Committee Members will take place during the ACRIN 2009 mtg on Wednesday, Sept 30, 2009 at 5-6 PM; on-site RSNA staff to provide additional details
- Drs Sullivan and Judy to map-out agenda for next group call, scheduled for Tuesday, Oct 13 at 11 am CDT

RSNA 2009 Activities

- QIBA Working Meeting, Wednesday, Dec 2, 2009, 2:00-4:00 PM
- All interested welcome to participate in QIBA Tech Ctte breakout sessions

Next Steps

- Dr Crapo to circulate participant list from Feb '09 COPDGene f2f
- Drs Crapo and Sullivan to discuss possible QIBA COPD/Asthma f2f in Spring 2010
- Drs Sullivan and Judy to map-out agenda for next group call, scheduled for Tuesday, Oct 13 at 11 am CDT
- Mr Buckler and Dr Judy will attend COPDGene Fall 2009 Investigators Meeting, Denver, CO, Nov 9-10, 2009
- Guidance and feedback welcome from all committee members
- RSNA staff to schedule a follow-up COPD Phantom Design call