

QIBA VoICT Tech Ctte Weekly Update
Monday, December 20, 2010 at 11 AM CST
Call Summary

In attendance

Andrew J. Buckler, MS (QIBA Program Director)
P. David Mozley, MD (Co-chair)
Lawrence Schwartz, MD (Co-chair)
Maria Athelougou, MD
Heidrun Endt
Charles Fenimore, PhD
David Gustafson, PhD
Philip Judy, PhD
John Lu, PhD
Daniel Nicolson
Kevin O'Donnell

Nicholas Petrick, PhD
Anthony Reeves, PhD
Yuanxin Rong, MD, MPH
Ganesh Saiprasad, PhD
Daniel Sullivan, MD
Ying Tang, PhD
David Vining, MD
Binsheng Zhao, DSc

RSNA
Joe Koudelik
Madeleine McCoy

Biomarker Qualification Review Team (BQRT) Questions Regarding the Briefing Document

- QIBA and the fNIH cosponsoring the qualification of Volumetric CT imaging for regulatory decision making in clinical trials for cancer
- Per our request letter, the FDA's BQRT met in Sept/Oct 2010 and asked for a Briefing Document with their (FDA) specific questions that need responses
- 2 phases involved
 - Pre-consultation with FDA (with the BQRT)
 - Qualification itself (later stage)
- Claims Language Discussed
 - Need clear statement of what the VoICT Claims are and determine how to pursue appropriate groundwork in support of Claims
- Evaluate correlations with outcomes
 - Early identification of progression
 - Confirmation with pathological outcomes
- Balance needed for FDA submission; narrow vs broad focus discussed
- Dr Schwartz to wordsmith claims and proposal to complete the qualification (full data package) in Briefing Document; all input welcome
- Dr Gustafson to help wordsmith response to BQRT question# 3
- Claim for Volumetric CT in relation to RECIST discussed
 - CT Volumes are to replace longest diameter (used in RECIST) metric
 - Replacing uni-dimensional (longest) diameter as proxy for tumor mass confirmed; goal is to use volume as basis to make critical response assessments (NOT replacing the rest of what RECIST specifies)
- Profile v2.0 is our representation of what is actually being qualified. That is, the scope and content of Profile v2.0 is our definition for the standardized marker as it would be qualified.

Next steps:

- Dr Schwartz to wordsmith claims and proposal to complete the qualification (full data package) in Briefing Document
- Dr Gustafson to help wordsmith response to BQRT question# 3
- RSNA staff submit brief text on the build-up of Quantitative Imaging Reading Room showcase at the RSNA Annual Meeting and send to Dr Tang
- Next call scheduled for Monday, Jan 10, at 11 am CST