

QIBA Quantitative CT Committee

Monday, January 25, 2010

11 AM CST

Call Summary

In attendance

Andrew Buckler, MS (co-chair)
P. David Mozley, MD (co-chair)
Lawrence Schwartz, MD (co-chair)
Maria Athelougou, MD
Rick Avila, MS
Kristin Borradaile, MS
Charles Fenimore, PhD
John Fraunberger
Philip F. Judy, PhD
Michael McNitt-Gray, PhD
James Mulshine, MD
Kevin O'Donnell

Anthony P. Reeves, PhD
Yuanxin Rong, MD, MPH
Matthew Silva, PhD
Daniel Sullivan, MD
Binsheng Zhao, DSc

RSNA

Fiona Miller
Susan Anderson, MLS
Joe Koudelik

Informatics infrastructure (Mr Avila and Mr Buckler)

- Mr Avila reviewed progress in the ad hoc group on data resources which met for the first time in week of Jan 18, 2010.
 - The ultimate goal is to facilitate the building of large public databases for research
 - The group aims to identify issues and solutions to accelerate development of open databases
 - Would like to explore compiling data from existing clinical trials, as well as evaluate what has worked/didn't work in the past
- Mr Avila reviewed experience with *Give a Scan* with the Lung Cancer Alliance as an example
 - Patients are directed to tools to anonymize scans; anonymization is a critical issue
 - Mr Avila's group accepts the data for curation using the open source MIDAS tool
 - The curation process is cost-, labor- and time-intensive.
- Interest in application of AVT as it presently exists to analyze 1A data as well as to envision an improved AVT, NBIA, AIM
- caBIG has interest in supporting informatics extensions and may be able to offer support to QIBA
 - caBIG is linking images to standardized vocabulary databases
 - caBIG tools and software are all free, open-platform, open-source and distributable
- The first level of activity is supporting clinical trials and research activities; next level will be dissemination into clinical practice, e.g. structured reporting, with controlled vocabularies, automation and harmonized with quantitative image readouts
- The RSNA has an active committee on structured reporting which has posted structured reporting templates
 - The RSNA 2010 Quantitative Imaging Reading Room will also feature structured reporting
- QIBA Profiles will have semi-standardized, modular portions which may be used in multiple profiles
- Dissemination strategy needed to get structured reports into the radiology community

Emerging Roadmap

- Following discussion with Federico Goodsaid at FDA, a number of steps in the process to qualify imaging biomarkers have been outlined (see attached document)
- The engagement process with FDA is initiated with a Request Letter from a consortium such as QIBA; subsequent steps include preparation of a Briefing Document and a Full Data Package
 - The steps are well-aligned with the European 'Advice' processes
- Mr Buckler reviewed the Table of Contents of a sample Briefing Document, to include:
 - Literature review (completed with *Annals of Oncology* submission)
 - Data (e.g. data from Groups 1A-B-C, Volcano; work of this QIBA collaboration)
 - Retrospective analysis of existing clinical data; reinterpreted based on new biomarker (examples presently underway under the auspices of QIBA)
 - Plan for collection of future data, e.g. Roadmap
- Consider performing a mock / internal test of the process to insure all pieces complete

Next Steps

- Continue discussion on the Roadmap draft and submission to FDA
- Continue framing of QIBA activities and outline of QIBA process