QIBA VolCT Update WebEx
Monday, March 30, 2009
11AM (CST)

Call Summary

In attendance:

Andrew Buckler, MS (Co-Chair)
Rick Avila, MS
Johann Kim, MD (for Dr Athelogou)
Charles Fenimore, PhD
Robert Ford, MD
David Gustafson, PhD
C. Carl Jaffe, MD
Despina Kontos, PhD
Michael McNitt-Gray, PhD
James Mulshine, MD
Daniel R. Nicolson
Nicholas Petrick, PhD

RSNA
Joe Koudelik
Mary Cerceo

General Discussion:

IIBE

- The tentative IIBE name and logo was introduced and discussed (Mr. Buckler)
- Efforts were made to choose a name/acronym similar to the one used by IHE - for look and recognition, but do not need to stay this way
- Greater definition still needed for the IIBE
- IIBE vs. IHE - Understanding the differences needed
    - No distinction made between drug development and clinical use
    - Connectathon doesn't make sense for IIBE
    - Use generalized concepts - similar notations, terms, etc
    - IIBE has a different process flow than IHE

QIBA Goal with Profile Claims

- QIBA efforts
    - Define goal
    - Conduct groundwork
    - Results in profile and qualification data
    - QIBA establishes the predicate to be referred to by vendors when developing new products
- Profile claims will be the predicate that a method works
- Biopharma and vendors don't need to establish whether a method works, only establish that their devices can perform the method. This would eliminate much ground level work and allow biopharma and vendors to focus more on technology.
- Need FDA to agree that vendors can use the IIBE profile claims as predicates (performance testing to be done)
- Greater FDA involvement with IIBE due to qualification of data needed
    - More regulatory people need to weigh-in
    - Dr. Louis Marzella has begun discussions whether a change in law is required, or just an interpretation already possible
- Clinical Trials / UPICT also need to use profiles - additional protocol customer
    - Proffered protocols turned into consensus protocols, then used in clinical trials

- Clinical expertise needed to describe profiles (claim side) to have related set of claims captured in one profile

Software Changes

- Software changes produce their own problems
- Software is an evolutionary product - never static
- More than simple code changes are involved
- QIBA FDG-PET/CT Software Version Tracking Technical Subgroup already addressing this issue
  - This work could cross-pollinate the DCE-MRI and Volumetric CT Technical Committees

CAD Corollary

- CAD domain issues need to be addressed
- The (stakeholder) community should address this issue, not individual companies - more feasible for all participants
- Systematic approach needed

FDA Input Needed

- FDA requires data to support profile claims
- Specifics of how a product will be used is needed - implementation details
- Core set of testing data (reference) needed to move forward with FDA
- Proposed method of development needed
- Involvement with CDRH (Center for Devise and Radiological Health) proposed
- Dr Petrick to assist with communication between QIBA and the FDA regulatory side

QIBA VolCT Subcommittee Updates

Group 1A (Dr. Petrick)

- Pilot study done
- 2 readers used (RadPharm)
- 10 nodules measured
- Preliminary data to be added to QIBA Wiki
- Wait 6 weeks; then repeat readings (April timeframe)
- Pivotal study done by late May ‘09
- 1D, 2D, 3D complications with bias and variance
- Two analysis software packages used (1D and 2D with one, 3D with another)
- Working out final issues now

Group 1B (Dr. McNitt-Gray)

- Two experiments outlined
- Two group calls scheduled for this week to tighten-up experimental design/procedures
- Anticipating Group 1A results to learn from
- Exp#1 Inter and intra-reader bias and variability
  - LIDC contoured data used as “standard” and compared to RadPharm reader results
- Exp#2 Extension of the MSK Coffee Break Experiment

- Reader variability under no change conditions

Group 1C (Dr. Fenimore)

- Group is at the planning stages
- Discussions continue over overall objectives
- Goals
- Inter-clinical comparisons affects of volumetric variance across various scanners
- How specify the protocol for different systems to make comparison
- Capture how data collections are staged
- ACRIN 6678 and NLST studies listed scanner parameters for equilibrating a manufacturer's equipment being used in the study - to be used as reference
- Need phantom ground truth (i.e. FDA phantom) for comparison
- Strawman proposal drafted - two arms of the study proposed
    - Mimic the ACRIN 6678 and NLST scanner parameter settings
    - Work with medical physicists to develop our own performance specifications

RSNA 2009 Annual Meeting

- What will be the QIBA role at the "Reading Room of the Future" showcase?
- Submission process and guidelines to submit scientific poster materials needed

Next Steps:

- Resume review of Claims/Details
- Circulate Dr Fenimore's updated strawman (Wiki link) once ready (RSNA staff)
- Provide more details concerning QIBA scientific abstract submission for RSNA 2009 (RSNA staff)
- Dr Petrick to assist with communication between QIBA and the FDA regulatory side
- Next call scheduled for Monday, April 6, 2009 (11 AM CDT)