QIBA Volumetric CT Group 3A Update

Thursday, March 29, 2012; 11 AM CT Call Summary

In attendance RSNA

Maria Athelogou, PhD (Chair) Hyun Grace Kim, PhD Julie Lisiecki

Hubert Beaumont, PhD Ying Tang, PhD

Preparation of abstract materials for RSNA 2012

Andrew J. Buckler, MS

 Team worked on the abstract document, honing the experiment description and the clinical relevance section to meet the character limit

Luduan Zhang, PhD

- Statistics were added to provide weight to the description
- Team was also advised to include FDA authors and allow for FDA preview prior to submission
- Dr. Kim selected as lead author to submit draft after checking in with FDA colleagues to meet 3/31 deadline of 12 noon CT

Presentation to the CT Volumetry Committee on 3/26

• Group 3A presentation was very well-received and the team is pleased as their work was recommended as an example for other teams

Pilot Study Results Update

- Pilot results are complete with the exception of the statistical analysis, which is still in draft form
 - o These results are also posted to the QI-Bench site: www.QI-Bench.org
- RSNA staff to forward results to participants without statistical analysis

Pivotal Study Update

- Interpretation of power calculation needed to finalize Pivotal Study
 - o Currently, 40 fully-curated cases are available with 408 lesions
 - o Dr. Kim to review power study prior to next meeting and email comments to team
- Timelines may need to be extended
- Forms for participation must also be finalized

Next steps:

- Dr. Kim to review power study prior to next meeting and email comments to team
- 3A Challenge organizers to continue work on curation of the pivotal data for next phase
- Mr. Dima and Mr. Buckler to work on pivotal study documents
- Drs. Kim, Lu and Saiprasad to prepare statistical design (power study) documents based on guidance from Dr. Athelogou by the end of March
- RSNA staff to forward PILOT study results to participants without statistical analysis
- New Friday time for calls TBD by group

Next call: Thursday, April 5, 2012 at 11:30 AM Central (Daylight) Time - (special time)