

QIBA CT Small Lung Nodule (SLN) Biomarker Ctte (BC) Call

16 May 2019 at 11 AM CT

Call Summary

In attendance:

David Gierada, MD (Chair)

James Mulshine, MD (Chair)

Rick Avila, MS

Artit Jirapatnakul, PhD

Nancy Obuchowski, PhD

Anthony Reeves, PhD

David Yankelevitz, MD

RSNA:

Joe Koudelik

Julie Lisiecki

Moderator: Mr. Avila

Software Conformance Testing:

- Mr. Avila has been planning for conformance testing of various analysis software packages
- Volume precision measurements will be performed on zero-change (real nodule) clinical datasets
- Zero change datasets with 5 repeats provided by Dr. Yankelevitz
 - Dr. Yankelevitz provided 72 cases; 58 were workable
 - Dr. Yankelevitz has a larger dataset of “coffee break” scans, with 3 to 5 repeats on small nodules from multiple sites
 - This dataset is being curated by his data manager but may soon become available for testing
 - With 3 timepoints, if 2 of the timepoints are close, one can be confident that there is no change, or “zero-change”
 - Subjects scanned months apart with different scanners, protocols, and positions
 - CTLX1 phantoms with embedded ellipsoids
 - Evaluate measurement precision, bias, and linearity in synthetic objects
 - Consider looking at volume measurement prediction performance, though this is not needed for software conformance

Clinical Zero Change Testing:

- All datasets will be acquired with a conformant CT acquisition protocol and a medium level of CT image quality characteristics

CTLX1 Phantom with Ellipsoid Modules: Scan and Measure:

- The CTLX1 phantom will be scanned 3 times using a medium level of CT IQ characteristics (resolution, sampling, noise, etc.)
- Ellipsoids will be volume measured and mean and standard deviation will be calculated
- This will require one site for conformance of software name / version
- It would be ideal to get data from at least two sites using the same phantom

Bias assessments:

- Claim 1 in the Profile assumes no bias; therefore, it must verify that the actor’s bias is <5%
- With three replicate scans of the CTLX1 phantom, it is possible to estimate an actor’s bias to within $\pm 1\%$
- Even if an actor’s bias is 4%, we can verify, with 95% confidence, that bias is <5%
- This will then be repeated for each of the 5 ellipsoid sizes

Next steps toward Claim-confirmed:

- Sorting out the different scanners, protocols, software, etc., is needed to consider a claim-confirmed study
- Mr. Avila hopes to develop methods for testing software conformance for the software vendors and clinical sites to show that they meet the claims
- At least two sites are needed to perform this testing
- Results will be pooled in order to get a tight confidence interval and could influence work toward claim-confirmed status for the Profile
- Until the data from Dr. Yankelevitz can be reviewed, it will not be known how consistent the scan technique is and whether it conforms to the Profile specifications
- Drs. Obuchowski and Yankelevitz to consult offline regarding different ways to analyze the coffee-break scans
- Dr. Yankelevitz has now collected over 300 cases and would like to help the Small Lung Nodule effort by allowing them to be studied
 - Bias correction was not used at first and will need to be added
 - With the use of the Lesion Sizing Toolkit, the time-consuming nature of this work will be reduced
- Mr. Avila expects some trouble with bias measurements, as typically spheres are used for evaluation, and the phantom does not have spheres
- Mr. Avila would also like to target technical conformance at two more sites

CTLX2 (next ellipsoid phantom):

- The new phantom will have a special insert that allows mass to be added using multiple water jackets
- Optimum weight with water added will be 40 pounds; empty phantoms will be light in weight for shipping
- The new phantom will allow optimization of image quality with respect to dose for solid and non-solid lesions

Other topics:

- As more new-model scanners are reporting higher in-plane resolution and as reconstruction methods rapidly change, resolution across the same image may vary
- When resolution is assessed, it is important to make sure that work is carefully checked
- Mr. Avila is working on adding the ability to provide the coefficient of variation for part-solid and solid nodules
- Aspect ratio may aid with this measurement, and if numbers are within a certain range, it should be ok to include them

Next calls and deadlines:

- CT Small Lung Nodule BC: *tentatively scheduled* for June 20th at 1 pm CT *if needed after the QIBA face-to-face meeting for follow up.*
- Also – for CT Coordinating Committee members, the next call is Monday, August 19th at 11 am CT