QIBA Project 15(a). Extension of Assessing Measurement Variability of Lung Lesions in Patient Data Sets: Variability Under Clinical Workflow Conditions

This project seeks to extend that previous effort by altering the reading paradigm to more realistically reflect conditions encountered in clinical trials and clinical practice. In the proposed project, readers would be allowed to read cases side by side and would be allowed access to both visual results of previous markings as well as the quantitative results of those measurements (diameter, volume, etc.). In order to reduce the potential of bias from reading repeat CT scans in a side by side paradigm, we propose to <u>randomly introduce cases in a designed block that do have some change in them</u>; in this way, readers will not have the expectation that all cases will have "no change".

3-month progress

- Experimental design with side by side comparisons allowed, which has been approved by QIBA VoICT 1B group.
- 2. Discussions have started for design of the next phase reader study in which readers will be allowed to view both datasets when performing the second set of measurements.
- 3. Data analysis plan is in the process for the consideration in adding non-coffee break data set. A block randomized order for reading is in progress with the discussion of the next phase.
- 4. Data analysis plan in progress
 - a. Investigation into minimum detectable change using revised reading paradigm
 - b. Inter- and intra-reader variability analysis

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