QIBA fMRI Biomarker Committee (BC) Call

Wednesday, August 7, 2019 at 11 AM CT Call Summary

In attendance RSNA staff

Feroze Mohamed, PhD (Co-chair) Jay Pillai, MD (Co-chair) David Soltysik, PhD (Co-chair) Andrew Kalnin, MD Ho-Ling (Anthony) Liu, PhD Nancy Obuchowski, PhD David Scott, PhD James Voyvodic, PhD Zhiyue (Jerry) Wang, PhD Joe Koudelik Susan Stanfa

Madaustan Du Calturil

Cathy Elsinger, PhD

Moderator: Dr. Soltysik

Review of Previous Call Summary

The 07.17.2019 call summary was approved as presented

Profile v2.0 (language-mapping)

- Due to greater clinical interest for language-mapping, efforts were redirected from Profile v1.0 (motor) to v2.0 (language)
- Dr. Liu, v2.0 Profile editor, provided a progress update, and indicated he planned to dedicate more time to the Profile in September
- While most Profile v1.0 content can be applied to Profile v2.0, Claims will substantially differ
- A literature search for Profile v2.0 has begun and a review of repeatability studies is underway with the goal of identifying a suitable quantitative index
- Overviews on two reproducibility/repeatability/reliability studies of language fMRI were provided:
 - Voyvodic J. <u>Reproducibility of single-subject fMRI language mapping with AMPLE normalization</u>. *J* Magn Reson Imaging. 2012.
 - 12 healthy volunteer subjects
 - Performed well on language-mapping task (sentence completion) with little motion
 - 1 6-hour test-retest period
 - Agarwal S, Hua J, Sair HI, Gujar S, Bettegowda C, Lu H, and Pillai JJ. <u>Repeatability of language fMRI</u> <u>lateralization and localization metrics in brain tumor patients</u>. *Hum Brain Mapp*. 2018.
 - Tasks included sentence generation (37 patients) and silent word generation (78 patients)
 - Test-retest period was composed of consecutive runs within the same scan session
 - Good data for based on patients repeating a task were obtained
 - It was noted that disparity in Laterality Index (LI) calculations between the two studies is likely
- Guidance developing Claims based upon reviewed literature was requested
- Statistical methods used to calculate the true confidence intervals to achieve the Claim in v1.0 were explained
- Values in motor-mapping Profile v1.0 were conservative; language-mapping v2.0 Claims to be more accurate
- Profile v2.0 will not include a "ground truth" Claim, but rather a reproducibility Claim re: BOLD activation
- It was mentioned that we need across-session studies to make claims about language fMRI reproducibility
- It was determined that additional data need to be reviewed and analyzed before Claim values can be established; 300 available datasets deemed more than enough
 - Discussion regarding what is needed for a Profile Claim to help steer data analysis
 - Within-subject variability to be the focus, since bias is not understood (no phantom studies to compare in terms of truth)

- Caution voiced re: questionable assumptions between DRO and human task comparisons; this was deemed a risky direction to pursue
- DROs can be generated if necessary; Dr. Voyvodic has motion DROs with language data with variability in the way that tasks were performed (variability based on head motion and test performance could be added)
- Suggestion to incorporate center-of-mass data based on published results
- Benefits of motion from empirical data vs. other modeled DROs data were discussed
- Challenges remain re: how to analyze the data and deciding which scans would meet the qualifications for the Claim
 - o Decide how to calculate motion, task performance, etc. and what is acceptable
 - Alternative ways to assess performance in fMRI when evaluated in terms of patterns of activation in the task, as opposed to measuring task performance
 - o Parameters/qualifications for a good language scan to be defined
 - o How to make a scan reproducible and what degree of reproducibility is needed to be determined
 - Need to define laterality
 - o These issues will need to be discussed at great length
- In Profile v1.0, the measurand (BOLD signal) was defined early in the Profile
 - In a good fMRI scan, i.e., subject successfully performs test with low imaging noise, a good BOLD signal map will result
 - Recommendation to also use BOLD signal as the measurand in v2.0, and focus on defining a good scan;
 if the scan is not good, the Claim would be irrelevant
 - o Amount of variability that would allow a good BOLD signal to be defined; most data to come from DROs
 - DRO data to be sorted for those that meet criteria for a good scan (has good BOLD signal)
 - Within-subject imprecision due to biology of patient, scanners, software, etc. needs to be determined

Next Steps

- Potential issues for v2.0 to be identified over the coming weeks
- Text will be copied from v1.0 and pasted into v2.0 where applicable

Next call: QIBA fMRI Biomarker Cmte call – Wednesday, August 21, 2019 at 11am CT - 1st & 3rd weeks of each month

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