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)	Andrew Kalnin, MD	David Scott, PhD	Joe Koudelik
Jay Pillai, MD (Co-chair)	Ho-Ling (Anthony) Liu, PhD	James Voyvodic, PhD	Susan Stanfa
David Soltysik, PhD (Co-chair)	Nancy Obuchowski, PhD	Zhiyue (Jerry) Wang, PhD	
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. **Reproducibility of single-subject fMRI language mapping with AMPLE normalization**. *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. **Repeatability of language fMRI lateralization and localization metrics in brain tumor patients**. *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 across-session studies are needed 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
  - 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
  - Parameters/qualifications for a good language scan to be defined
  - How to make a scan reproducible and what degree of reproducibility is needed to be determined
  - Need to define laterality
  - 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
  - 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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