

## QIBA fMRI Biomarker Committee (BC) Call

Wednesday, July 7, 2021, at 11 a.m. (CT)

### Call Summary

#### In attendance

Feroze Mohamed, PhD (Co-chair)

David Soltysik, PhD (Co-chair)

Shruti Agarwal, PhD

Ichiro Ikuta, MD, MMSc

Andrew Kalnin, MD

Ho-Ling (Anthony) Liu, PhD

Nancy Obuchowski, PhD

Bram Stolk, PhD, MBA

James Voyvodic, PhD

Francisco Zamorano, PhD

#### RSNA staff

Joe Koudelik

Susan Stanfa

#### Review of Previous Call Summary

- The 06.16.2021 call summary was approved as presented

#### fMRI Language-Mapping Profile v2.0

- Dr. Voyvodic has expanded his focus on laterality by comparing different ways of calculating laterality index (LI) in addition to only 50% AMPLE thresholding and AMPLE-weighted values
- LI for 10 different threshold methods were calculated for 1,097 language fMRI maps and it will be determined how differences in LI calculation methods affect reproducibility
- An optimal peak in terms of T-Value reproducibility was investigated; the AMPLE thresholding method may be best, but percentage (either 30% or 40%) to be determined
- Spatial smoothing would affect peak but not the result
- Dr. Voyvodic to submit two papers for publication based on the language-mapping reproducibility study, one on laterality and the other based on cluster location and size of cluster activation
  - This work is informing the fMRI Language-Mapping Profile v2.0 and will support its Claims

#### fMRI Language-Mapping Profile v2.0 Claim Development

- Claim 1: If X, Y, Z is the measured location of the weighted center-of-mass of a single focus of fMRI language activation (wCMA), then the 90% confidence interval for the X, Y, Z of the true wCMA is +/- 10 mm in any direction. (Note: the 85% confidence is +/- 7 mm, the 95% confidence is +/- 20 mm)
  - Dr. Voyvodic supported the structure of the Claim, but values will be confirmed when his paper is finished
- Original Claim 2: The Laterality Index (LI) will be within 0.6 of the true LI (95% confidence). If the Laterality Index (LI) is > 0.5 or < -0.5, it has a 95% probability of being the same hemisphere in a second run.
- Claim 2 was rewritten to match the standard format of QIBA Claims: If L is the measured LI, then the 95% confidence interval for the true LI is +/- 0.6; if the LI is > 0.5 or < -0.5, it has a 95% probability of being the same hemisphere in the second run"
- Dr. Voyvodic had plotted the LI value against the LI match probability and found that for LI > 0.4 or LI < -0.4, there is 90% confidence that the follow-up scan will result in the same laterality
  - 90% confidence was deemed insufficient for performing surgery on a single patient, as it would signify a 10% chance of producing aphasia
  - This confidence interval would be acceptable for use in clinical trials with 1,000 subjects
- Peak and center of mass (CoM) are not always in the same location, depending on the shape of the activation cluster; adding a separate diagnostic reliability Claim related to peak was suggested
- A peak in one scan cannot be compared to CoM in another scan; further study would be needed to determine the relationship between peak and CoM
- CoM can be averaged, providing a more reproducible Claim; an average measure instills greater confidence than a single voxel

- Dr. Voyvodic to reference his data and review 300 voxels and their location; if close to each other, the peak would be a more trustworthy measurement than the CoM
- Claims for language-mapping for clinical trials vs. for diagnostic use in a single patient to be distinguished in the Profile
  - The use of QIBA Profiles is generally more targeted to clinical trials than to patient clinical care
  - At least two different scans should be done to demonstrate overlap of location and size of language activation to determine whether scans meet criteria and whether language maps are sufficient for meeting the Claims
  - Greater amount of activation overlap signifies a better scan
- Discussion re: including an explanation of context of use in clinical and diagnostic settings in the Profile, since claims for clinical trials vs. diagnostic reliability were deemed different
- Dr. Liu had already completed the framework of the fMRI Language-Mapping Profile in late 2019, with text copied and pasted from the Motor-Mapping Profile v1.0; it will be reviewed during the next meeting on July 21

**Next call:** Wednesday, July 21, 2021, at 11 a.m. CT (1<sup>st</sup> & 3<sup>rd</sup> weeks of each month)

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