QIBA fMRI Biomarker Committee (BC) Call
Wednesday, August 21, 2019 at 11 AM CT
Call Summary

In attendance
Feroze Mohamed, PhD (Co-chair)  Andrew Kalnin, MD  James Voyvodic, PhD  Joe Koudelik
Jay Pillai, MD (Co-chair)  Ho-Ling (Anthony) Liu, PhD  Yuxiang Zhou, PhD  Susan Stanfa
Cathy Elsinger, PhD  Nancy Obuchowski, PhD

RSNA staff

Moderator: Dr. Mohamed

Review of Previous Call Summary
- The 08.07.2019 call summary was approved as presented

Profile v2.0 (language-mapping)
- Though Profile v1.0 is on hold, fMRI BC members are still welcome to propose changes
- Discussion continued, regarding whether additional data needs to be analyzed and reviewed for v2.0
  - Challenges remain re: methodology for analyzing the data and deciding which scans would meet the qualifications for the Claim
  - Dr. Voyvodic has plenty of usable data, but there are potential qualitative and quantitative issues with it
- Reminder that Profile v2.0 will not include a “ground truth” Claim, but rather a reproducibility Claim re: BOLD activation; within-subject variability to be the focus, since bias is not understood (no phantom studies to compare in terms of truth)
- 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
- Dr. Liu reviewed two reproducibility/repeatability/reliability studies of language fMRI since the Aug. 7 call
  - Disparity in Laterality Index (LI) calculations between the two studies is likely
  - Guidance needed with Claim development (i.e., converging data from reviewed literature into Claims)
- Dr. Liu, v2.0 Profile editor, provided a Profile-writing progress update
  - Most text from v1.0 is applicable to v2.0
  - Minimal modification to the Executive Summary is needed
  - Only a couple of minor revisions to the introductory text are needed in Section 2: Clinical Interpretation
  - While most Profile v1.0 content can be applied to Profile v2.0, Claims will substantially differ
  - Additional data need to be reviewed and analyzed before values for a second Laterality Index (LI) Claim can be determined; a placeholder will be added in the meantime
- Section 3: Profile Activities
  - Minor revisions are needed throughout these subsections
  - Section 3.9: Image Analysis to be dedicated to calculating center-of-mass and LI biomarkers
  - Most content in Section 3.10: Image Interpretation & Distribution can be used with minor revisions
- Section 4: Assessment and Procedure
  - Most of the introductory content can be reused
Center-of-mass language in Section 4.1: Assessment Procedure: MRI Equipment Specifications and Performance can remain, and LI specification will be added
Additional discussion needed re: Neurovascular Uncoupling assessment procedure

- Appendices
  - A: Acknowledgements and Attributions to be updated
  - B: Conventions and Definitions can be left as is
  - C: Paradigm Specification to be completely revised to include LI
  - D: Most of the scanner information in Device-specific Parameters to Achieve Claim Conformance can remain
  - E: fMRI Data Processing; text can be reused if similarities exists between motor and language
  - F: Selecting a threshold criterion for identifying active voxels can be reused

- Recommendation to closely review each section of the Profile and remove any text that is not conducive to achieving the Claims
- Significant unpredictability and complication due to the location of language areas and weaker signal will present challenges for Profile v2.0; data analysis procedures/text used in v1.0 will be insufficient
- Neurosurgeons concerned with aphasia due to tissue resection, not whether activation areas are associated with a specific task
- Rather than using clinical goals, the fMRI BC will consider how well tasks used for brain mapping can be used as a reference for a generic activation
- Suggestion to include only scans of right-handed individuals, which was deemed important for consistent language-mapping, but not as much for motor-mapping
  - It was noted that limiting to only right-handed people would make the Profile less useful by skewing laterality issues
  - Suggestion to make various maps under different conditions, stratifying groups based on laterality
  - This topic to be included in a discussion section of the Profile, but will not be incorporated into Claims
- Across-session studies are needed to make claims about language fMRI reproducibility
- Recommendation to review scans from 1,000 human subjects and empirically determine what language ROIs look like in general
  - Areas of activation will be similar, but they will activate to different degrees among different individuals in response to different tasks
  - Suggestion to calculate six areas in each hemisphere and note patterns in language areas
- Neurosynth, a platform for large-scale, automated synthesis of functional magnetic resonance imaging (fMRI) data, was referenced
- Dr. Voyvodic has been drafting a publication on motion DROs
  - Recommendation to make summary tables and/or DROs available for those who want to download specific types of data to study head motion
  - Dr. Voyvodic to follow up with RSNA staff re: making DROs available on QIDW - the number of datasets that would be useful and whether they should be packaged in subsets to be determined

Next call: QIBA fMRI Biomarker Cmte call – Wednesday, September 4, 2019 at 11am CT - 1st & 3rd weeks of each month

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