

QIBA fMRI Biomarker Committee (BC) Meeting

Wednesday, June 7, 2023, at 11 a.m. (CT)

Meeting Summary

In attendance

Feroze Mohamed, PhD (Co-chair)

Jay Pillai, MD (Co-chair)

David Soltysik, PhD (Co-chair)

Shruti Agarwal, PhD

Andrew Kalnin, MD

James Voyvodic, PhD

Francisco Zamorano, PhD

RSNA staff

Susan Stanfa

Review of Previous Meeting Summary:

- The 05.03.2023 meeting summary was approved as presented

Topics Discussed:

- Updates to checklists in Profile sections 3.8: Subject and Task Handling, 3.9: Image Analyst, and 3.10 Conformance Testing

Action Items:

- Profile to focus on explaining to clinicians how to perform the scan, quality control, and to distinguish maps that meet the Profile's pre-criteria (peak of t value of 8) from the ones that do not
- Conformance testing was deemed useful for clinical trialists to prove that they can duplicate results, but will be put on hold until enough DROs and software tools could be made available
- Activation map as a measure of task performance may be the most practical method of assessment in language mapping
- Assessment of fMRI laterality index reproducibility checklist to remain in the current version of the Profile
- Only Profile sections up to 3.9: Image Analyst Checklist is required for clinicians; suggestion to include the remaining sections in an Appendix or indicate that they are optional steps for those users who need replicate the Profile's Claims, e.g., clinical trialists
- Checklists to be actor-oriented and redundancy across them to be eliminated; "Conformance Tester" was a 3.1 Site Checklist actor

Next Steps

- **Next meeting:** Wednesday, June 21, 2023, at 11 a.m. CT (1st & 3rd weeks of each month)
 - Discussion on meaning of "conformance" in Section 2, e.g., downloading DROs and reproducing Claims vs. a site's ability to complete the steps as specified in the Profile
- An updated Profile will be distributed
- Feedback to be solicited from Dr. Elsinger regarding what an image analysis tool manufacturer needs in order to do conformance testing
- Dr. Storrs to update ROI Identification section text in the Appendix re: registration process
- Discussion on whether to add a 3rd Claim to be continued
- Next steps following completion of the Profile:
 - Circulation for full BC internal review followed by a vote-to-release for Stage 1: Public Comment
 - MR CC vote-to-release will follow
- White paper to be drafted once the Profile is completed and Dr. Voyvodic's reproducibility study data has been published