

QIBA fMRI Biomarker Committee (BC) Call

Wednesday, March 7, 2018 at 11 AM CT

Call Summary

In attendance

Feroze Mohamed, PhD (Co-chair)

Jay Pillai, MD (Co-chair)

David Soltysik, PhD (Co-chair)

Cathy Elsinger, PhD

Edward Jackson, PhD

Flavius Raslau, MD

James Voyvodic, PhD

RSNA

Joe Koudelik

Susan Stanfa

Review of Previous Call Summary

- The 02.07.18 call summary was approved as presented

fMRI BC Call Attendance – Suggestions for Increasing Participation

- Discussion on whether efforts should be directed toward fostering more enthusiasm for the group's current work or to change the focus to something that might be more interesting to members
- Suggestion to poll fMRI BC members and ask why they have not attended calls
 - They may have been engaged in the past but eventually lost interest or disengaged as a result of the fMRI BC meeting certain objectives
 - What they think would make these calls more appealing to them, e.g. is a change of direction needed, have the committee goals already been met, etc.?
 - Perhaps interest will increase with work on more clinically relevant Profile 2.0
- Suggestions to head in another direction regarding clinical trials and using another biomarker
 - Discussion on field-testing and sites that would participate
 - Would need to define what fMRI field-testing involves; a checklist would be required
 - It may help to imagine what sort of clinical trials might be interested in some way of measuring reproducibly, based on signal activation:
 - center of mass
 - center of mass and spatial extent
 - spatial extent and amplitude
 - It was noted that NIH regulations have become much more stringent regarding the definition of a clinical trial and they continue to evolve.
 - Additional discussion needed on quantitative fMRI and how it might be relevant to clinical trials (in the generic sense); might fMRI be eventually used as an assay?
- One idea related to the use of fMRI in the area of pain management; perhaps it would be useful to localize a brain area (i.e. point of stimulation for external devices) for pain or seizure management
- It was agreed that task-based fMRI localization of activation may be combined with transcranial magnetic stimulation (TMS), either in a clinical trial or assay
- Resting state fMRI also has been used for targeting interventions / specific therapies
- Having a check list as a primary guide for multi-institutional testing would be a practical next step

- Discussion on whether fMRI is quantitative enough to be useful as an assay, irrespective of its subsequent application
 - Additional consideration needed regarding uses of a quantitative fMRI Profile
 - The profile may be used for general fMRI standardization across multiple sites vs. specific clinical/research applications.
 - This Profile is useful in terms of establishing a fundamental standard (starting with basic motor-mapping) upon which future, more complex efforts (i.e. language mapping) may be built
- Some software companies have begun to claim QIBA compliance/conformance without demonstration of this
- Many sites are routinely using motor and language mapping for pre-surgical planning, which would be combined with DTI
- Decision to focus on Profile v1.0 checklist for now, then revisit issue of low call attendance and possible new direction in the near future.

QIBA Checklist: “fMRI Center of Mass Estimation for Pre-surgical Assessment (fMRI-CMA)”

- Discussion focused on review of the Claim-conformance check list and updates to be made
- Assessment procedures were divided into subsections by actor type; each actor has required performance tests to pass to prove conformance
- Actors (hardware, software, people) were identified
- For the Image Analysis Software checklist, the Profile user needs to:
 - Download a set of DROs
 - Determine the center of mass of activation for each DRO
 - Calculate the within-subject standard deviation across subjects
 - Determine if the value meets the profile claim
- Dr. Soltysik to update and circulate the latest version of the QIBA fMRI Checklist, which contains a validation list with elements drafted by both Drs. Soltysik & Voyvodic under the Image Analysis Software Checklist
- A possible item of discussion for the March 21 meeting would be to consider including a simple validation checklist using a single pair of DROs (which more sites are likely to do) in addition to a complete validation checklist using 30 pairs of DROs (which is something that fMRI software vendors should be motivated to complete, or make possible to complete, in order for their software to be QIBA-conformant)

Next calls:

- QIBA fMRI Bias TF call – Tuesday, March 13, 2018 at 1 PM CT
- QIBA fMRI Biomarker Committee call – Wednesday, March 21, 2018 at 11am CT

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