QIBA PET Amyloid Biomarker Committee (BC) Call
09 March 2018 at 9:00 AM CT
Call Summary

In attendance:

<table>
<thead>
<tr>
<th>RSNA</th>
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<tbody>
<tr>
<td>Dawn Matthews, MS, MBA (Co-Chair)</td>
<td>Tammie Benzinger, MD, PhD</td>
<td>Nancy Obuchowski, PhD</td>
<td>Joe Koudelik</td>
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<td>Satoshi Minoshima, MD, PhD (Co-Chair)</td>
<td>Paul Kinahan, PhD</td>
<td>Eric Perlman, MD</td>
<td>Julie Lisiecki</td>
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<td>Anne Smith, PhD (Co-Chair)</td>
<td>Adriaan Lammertsma, PhD</td>
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Moderator: Ms. Matthews

Profile Status:
- Significant Profile updates have been made, and 90 comments have been addressed
- The Profile will be available for BC distribution and review in approximately two weeks
- Any additional references to be added can be shared with Dr. Kinahan or RSNA staff: jlisiecki@rsna.org
- Dr. Benzinger is drafting a manuscript that contains useful PET/MR data; once published, it will be cited in the Profile
- The Claim and Clinical Utilization sections of the Profile have been updated and include:
  1. Powering of a clinical trial to measure the rate of amyloid accumulation
  2. Powering of a clinical trial to measure a reduction in the rate of amyloid accumulation (e.g. due to treatment intervention)
  3. Confidence interval around individual percent change
- The Profile is close to being voted as consensus (stage 2) and BC members should begin thinking about feasibility/conformance testing of the Profile and contacting possible testing sites that may have ties to ADNI, which would be helpful; greater networking with ADNI deemed useful to promote faster Profile integration within clinical trials

Proposed approach to address PET/MR in the Profile:
- Language in the Profile was updated to address PET/MR scanners as follows:
  - “PET/MR scanners are not strictly excluded in this version as long as the repeatability of the SUVRs from these scanners is conformant with the assumptions underlying the claims.”

Claim and Considerations:
- It is a technical performance claim
- The claim is applicable for within subject coefficient of variation (wCV) values from test-retest studies
- The claim is applicable for single or multi-center studies assuming that the same 18F-amyloid PET tracer, scanner, scanner software version, image acquisition parameters, image reconstruction method and parameters, and image processing methods are used for each subject at each time point as described in the Profile
- It is presumed that a) the wCV is constant over the range of SUVR values and b) any bias in the measurements is constant over the range of SUVR values (linearity).

Next steps:
- Ms. Matthews to post updated documents to the QIBA wiki
- Ms. Matthews to consult with Dr. Obuchowski offline regarding examples of outstanding items with the DRO
- Dr. Kinahan to work on recalibrating the DRO to address scatter correction artifacts using data from Ms. Matthews

NM WebEx Schedule:

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<th>Date</th>
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<tr>
<td>03/13</td>
<td>TC 99m Profile TF</td>
<td>04/06</td>
<td>FDG-PET BC</td>
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<td>03/16</td>
<td>I – 123 Profile TF</td>
<td>04/13</td>
<td>PET Amyloid BC</td>
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<td>03/23</td>
<td>NM Coordinating Ctte</td>
<td>04/20</td>
<td>I – 123 Profile TF</td>
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