QIBA Process Committee Call

Tuesday, June 16, 2020 at 2 pm (CT)

Call Summary

Attendees:			**RSNA Staff:**
Kevin O'Donnell, MASc (Chair)	Nancy Obuchowski, PhD	Gudrun Zahlmann, PhD	Joe Koudelik
Michael Boss, PhD (Vice Chair)	Daniel Sullivan, MD	Brian Zimmerman, PhD	Susan Stanfa
Alexander Guimaraes, MD, PhD			

Dashboard Profile Editors

- The group discussed updating the contact person to either Dr. Kinahan or Dr. Sunderland, as one is needed for future conformance work
    - Dr. Kinahan continues to champion this group in other areas, e.g., white paper published in *Radiology*
    - Dr. Boss to reach out to Dr. Sunderland, copying Drs. Subramaniam and Wollenweber
- Dr. Garra is transitioning to retirement mid-December and another US-SWS BC Profile editor contact is needed

Profile Stage 3: Technically Confirmed and Stage 4: Claim Confirmed

- QIBA groups have approached leadership with questions re: requirements to advance to stages 3 and 4
- DCE-MRI, DSC-MR, DWI, MRE and MSK BCs may all be approaching Stage 3 within the next 12 months; advancing to stage 4 could become a central issue for many BCs and guidance is needed
- There is a call scheduled on July 1 for QIBA Leadership and SIG leader, Dr. Zahlmann, to discuss MRE Profile conformance opportunities with Drs. Cole and Ehman
- Advancing to stage 3 requires more than drafting a checklist and sending it to 2-3 sites to review it to determine whether the requirements are feasible
    - It was noted that mismatches between Profile specifications and checklist items (should be 1:1 comparison) have been observed
    - It was recommended that the Profile be implemented, i.e., using human subjects, rather than sites reviewing the checklist for technical feasibility (section 3)
    - Dr. Obuchowski raised concern re: feasibility of Profile conformance (section 4) and that sites need to demonstrate that conformance activities can be performed
    - Though a conformance section may appear as "doable," sites need to perform the conformance tasks
- Dr. Obuchowski suggested that Technical Confirmation (stage 3) guidelines should focus on both Profile sections 3 (technical) and 4 (conformance)
- The DWI checklist contains significant Section 3.2 Site Qualification material, but lacks section 4 (conformance) detail
- As soon as consensus is reached, the burden for volunteer BC members to go through testing stages would need to be reduced
    - Discussion re: number of sites asked to implement a Profile (2-3 sites with multiple scanners)
    - Technical confirmation with a CRO holds extra value because Profile adoption in a clinical trial could be facilitated, which might eventually lead to claim confirmation; this would demonstrate that the Profile Claim is achievable
- Discussion re: whether DWI Profile conformance testing would need to be done individually, for each organ/disease site
    - It was suggested that the focus be on sites as "centers of excellence," vs. on disease site basis

- Discussion re: data needed back from a clinical trial to build up a database in terms of clinical confirmation; test-retest data would be ideal, but obtaining it may be unlikely
- Best approaches to achieve claim confirmation were considered
    - For Claim Confirmed, the assumption underlying the Claim, i.e., within-subject coefficient of variation (wCV) is being assessed; the Claim itself is not being tested
    - The original intention was that this is sufficiently powered data collection measuring the performance of sites (if one follows the requirements in the Profile, the performance will be as stated)
    - The CT Advanced Disease and FDG-PET Profiles Claim-confirmed studies consisted of multicenter studies of repeatability and reproducibility
    - Results need to match what the Profile Claim indicates should be the outcome when the Profile requirements are followed; wCV needs to be verified based on values found in the literature

- Stages 3 – 5 were summarized
    - Technical Confirmation = 2 - 3 sites are able to perform a Profile
    - Claim Confirmation = 2 – 3 sites are able to perform test-rest within a multicenter study using the Profile
        - Claim is loosely validated
        - This may be expensive and put significant burden on sites and patients, but would be realistic through QIBA partnership with an outside entity
    - Clinical Confirmation = comparison of several multicenter studies over a period of years
        - Claim is rigorously validated and requires substantial funding and infrastructure at a level outside of the scope of QIBA

- Discussion re: possible funding source support to help advance QIBA Profiles
    - NIBIB:
        - Buy-in is needed from NIBIB leadership
        - QIBA Profiles would involve clinical application and NIBIB is not involved in this aspect
        - Past barriers were lengthy checklists and Profiles that were not yet ready for “prime time”
        - NIBIB focuses on innovative technologies; advancing QIBs does not fall into this category
        - Dr. Sullivan was not optimistic re: future NIBIB support
    - Others considered were
        - Clinical institutions that are part of NCTN/NCI/QIN - commitment has been wavering
        - CROs deemed the most promising avenue
        - Foundations: join with existing up-and-coming studies that either have quantitative aims or could easily be extended to have some

Next steps:

- Subdivide Claim-confirmed stage description into distinct parts including (1) study design, (2) executing the study, and (3) analysis
    - Design Method to assess site performance (in terms of metrics in Profile Claims, e.g., wCV)
    - Recruit sites to follow the Profile and assess site performance
    - Analyze Site Performance Data and assess against Profile Claim
    - Review & Approve then Publish Claim Confirmed Profile

- In terms of potential funding sources, look for areas where biomarker adoption numbers are currently driving clinical care, i.e., the hot areas of QIB use

Next Process Cmte Call: Tuesday, July 7, 2020 at 2 pm CT (1st & 3rd weeks of each month)