QIBA Process Committee Call

Tuesday, February 2, 2021 at 2 pm (CT)

Call Summary

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

QIBA COI Policy

- Based on recent EC discussions, a policy has been developed to outline QIBA expectations re: COIs (e.g., issues that may emerge and how they will be addressed), to be posted on the QIBA Wiki following EC/SC approval
- When making decisions on behalf of QIBA, volunteers are entrusted to acknowledge when there might be a conflict and recuse themselves when appropriate

Hypothetical examples of COIs drafted by Dr. Sullivan were reviewed

COI Example 1 (abridged)

- A hypothetical BC member who is an employee of a software company that markets an algorithm relevant to the Profile under review by the BC
    - The company's FDA-approved algorithm uses one method of calculating a metric used in extracting the imaging biomarkers (IBs), but other methods also exist
    - QIBA member strongly advocates for Profile language favoring this method while other BC members support allowing for alternative methods that would also provide results in the same clinically relevant range
- To avoid a COI in this instance, the BC member would be expected to disclose the potential conflict to the BC; while they would not have to remove themselves from discussion, they would need to refrain from participation in decision-making on methods and recuse themselves from voting on any issues associated with their COI
- Suggestion to add language noting that QIBA avoids specifying or mandating particular methods, and instead seeks to set performance targets
- How QIBA Profiles interact with innovation in the marketplace may be another issue to consider

COI Example 2 (abridged)

- A hypothetical QIBA member is an academic investigator with a history of NIH funding for a research program on the IB under review by the BC
- Their lab has promulgated a particular theory about the biologic basis of the IB, and they have collaborated with a phantom development company to commercialize a phantom based on their theory
- The specifications in the Profile do not require that a particular phantom must be used, but the parameters are written to correspond to this one, specific phantom
- To avoid a COI in this instance, during the resolution of Public Comments, the BC member should acknowledge their intellectual and possibly financial COI and recuse themselves from the decision-making on specifications related to their COI
- A clear disclosure to the cmte is crucial, regardless of whether the longer-serving BC volunteers are aware of the COI, because newer BC volunteers may not be aware
- As in the other example, the contributions of the BC member with the COI would be welcome, but the other BC members would need to study the issue(s) and come to an independent decision based on sufficient justification or validation

- Moving forward, BC Co-chairs or RSNA staff to ask whether any participants have potential COIs at the beginning of specific sessions (e.g., public comment resolution discussions)
- Staff call notes will serve a record-keeping function when possible COIs are encountered
- Next step: Mr. O'Donnell to send the updated QIBA COI policy with examples to the EC/SC and post to the QIBA Wiki upon approval

Q1 CC Meeting Agendas: QIBA 2021 Campaign

- The Process Cmte offered to cede the time for the usual, standing Process Cmte update slot
- All CC leaders are requested to present an overview of the campaign and discuss the goals for Biomarker Committees to strive for in 2021
- The group discussed one aspect of the 2021 QIBA Campaign: Profile advancement from Stage 2 to Stage 3
    - It was noted that technical confirmation (TC) is not equivalent to first conformance testing, because the Profile may change as a result of TC testing feedback (i.e., some performance metrics or process steps may be revised)
        - If profile requirements do not change significantly as a result of conformance-testing feedback, test sites may be able to claim conformance
- Discussion re: increasing the number of sites needed for Technical Confirmation (aka, Feasibility Testing)
    - A requirement of three or more would provide diversity in testing sites; if the BC cannot get more than two sites to test their Profile, it could be an indication that the Profile is not viable
    - Mr. O'Donnell moved, seconded by Dr. Boss, that three or more sites will be required to complete Stage 3: TC
- The technical confirmation feedback resolution process was discussed
    - Collecting conformance testing feedback from sites
        - Would differ from the public comment process, with sites performing checklist requirements rather than merely reviewing the Profile text and providing input
        - One effective approach for collecting site feedback is to add a column to feasibility checklists for sites to indicate for each requirement, if the site can do it, whether they found it practical, and to add comments
        - The Process Committee plans to design a standardized form for this purpose
    - A standardized Technical Confirmation Resolution template will be used to compile feedback from TC sites, summarize cmte discussion, and record resolutions
    - Similar to the Public Comment Resolution sheets, BCs will use the TC document to address input received and make changes to the Profile as needed
- Before a Profile can be brought to BC voting members for TC (Stage 3) approval, final technical confirmation feedback resolutions documentation will need to be submitted and posted on the QIBA Wiki Comment Resolutions page
- Mr. O'Donnell to update the QIBA Wiki Technical Confirmation page and Profile Stages overview page in response to Process Cmte decisions

Next Process Cmte Call: Tuesday, February 16, 2021 at 2 p.m. (CT)