QIBA Process Committee Call

Tuesday, December 15, 2020 at 2 pm (CT)

Call Summary

Attendees:		**RSNA Staff:**
Kevin O'Donnell, MASc (Chair)	Nancy Obuchowski, PhD	Joe Koudelik
Alex Guimaraes, MD, PhD	Daniel Sullivan, MD	Susan Stanfa

Coordinating Cmte Criteria

- It was clarified that a formal change proposal is not needed; Mr. O'Donnell will provide a tracked-changes document for reference during the Dec. 17 SC meeting
- Discrepancies in terminology have been identified and the following changes have been made to the SC roster:
    - "Statistician" on the SC roster was renamed to "Metrology Cmte representative" to match the EC roster
    - "A Representative of the Sustainability Implementation Group," and "A Representative of the Secretariat (RSNA)" were added to the SC roster
    - Non-voting member positions:
        - RSNA Board "Liaison for Science" was specified
        - "AAPM" was added to the list of "Liaisons to partner organizations"
            - AAPM had been listed as a voting member position, only because a person that served in the Medical Physicist SC voting member position also happened to represent AAPM; AAPM representation on its own would not be a voting member role
- Changes to the EC roster included:
    - "NIH" was added to "NCI/QIB Liaison"
    - Dr. Sullivan noted that no successor is planned for his former External Relations Liaison role; discussion needed on whether this role will be filled, assumed by Drs. Hall or Guimaraes, or discontinued
    - It is expected that the representative from subordinate committees will be one of the co-chairs of those committees, but the co-chairs may choose to designate other members of their committee as a primary or alternate representative
- Modality CC roster:
    - The Scientific Liaison role has been discontinued
    - Voting privileges to continue for all BC Co-chairs, regardless of call attendance
    - To allow for flexibility during leadership transitions, number of Co-Chairs was updated to "Two or more"
    - "3-year renewable terms" specification was added to CC Co-chair, to match BC Co-chair guidelines
        - Some CC Co-chairs have held positions for 6+ years and may choose to continue or step down
    - Addition of 2 – 4 at-large voting members
    - A Process Cmte representative on CC calls is useful, but would not be deemed a voting member
    - Additional non-voting members (self-nominated or recommended) appointed by the Coordinating Committee to address potential new biomarkers or to provide specific expertise, e.g., clinical, technical, process, conformance, vendor representation, etc.
- SC members who are not on the EC are welcome to join EC meetings as guests
    - Discussion regarding how all SC members should be informed of EC calls and provided with materials
    - Suggestions included CCing non-EC SC members on EC communications, or posting information on the Wiki (barring any concerns about publication)
- Mr. O'Donnell to distribute information on these changes and consider this topic completed

Ballot Text Updates

- Staff have confirmed that the following text was incorporated into ballots:
    - "Please indicate whether this Profile meets the criteria for this stage, conforms to Profile guidelines and is of sufficient quality to publish"
    - If the BC or CC voting member is unable to review the Profile, they may abstain

Conflicts of Interest for Ballots

- A policy will be developed to outline QIBA expectations re COI (e.g., issues that may emerge and how they will be addressed) to be posted on the QIBA Wiki after approval
    - Dr. Sullivan's informational email regarding this decision has been distributed to QIBA members and he plans to follow up with another
- It was noted that because QIBA Profiles do not mandate products or services, the associated COIs issues are precluded
- Wording used by other groups (e.g., protocol approval committees, other organizations, AAPM, etc.) was evaluated and several policies were found to contain text regarding recusals
- QIBA voting members will be entrusted to acknowledge when there is a conflict and recuse themselves when appropriate
- Mr. O'Donnell pointed to the SIIM and IHE COI policy/statement examples that can be modified for QIBA's purposes
    - https://siim.org/general/custom.asp?page=siim_coi_policy

Profile Streamlining Efforts

- The recommendation to institute page limits was inspired by grant-writing experiences; an alternate idea was to establish a target page number per Profile section, or to suggest a limit on the number of requirements
    - An underlying point was that rather than including all requirements that might have an impact on the claimed variability, it would be helpful to focus on the smaller set of requirements that have a significant impact on the claimed variability; i.e. try to provide most of the benefit at a lower conformance cost
    - For example, maybe the BCs rank all of their Profile requirements based on how they affect the Claims, and consider omitting the bottom two
- The main benefits of reducing the length of Profiles are greater likelihood of publication and implementation
- For some Profiles, the Clinical Context section could be limited to a half page and merged into the Executive Summary for a total of ~one page
- All explanatory, supporting, or supplementary information should be included in appendices
- An additional proposal was to move checklists from the end of QIBA Profile documents to the beginning (Chapter 3), and move the existing Chapter 3 (which includes Discussion/clarifications and is organized by activity) to Appendix A
    - Most Biomarker Committees will likely still find the activity focus most productive for analyzing variability and reaching consensus on the requirements, but they can do their work in Appendix A and then generate the checklist when ready to publish
- Recommendation to replace paragraphs of text with a series of bulleted disclaimers in Section 1.3
- Discussion to continue re: other ways to help QIBA BCs determine what factors would and would not impact Claims, and how to shorten and increase Profile readability and usability while still having an accurate and complete document
    - Profile requirements to be re-evaluated (e.g., a Radiologist being board-certified is a reasonable standard-of-care for imaging, but may not impact Claim)

Proposal to modify the QIBA 3rd Party Validated Conformance Certification Mark based on Actors

- Conformance has been a binary (i.e., "all or nothing") construction; either a site can fully conform, or it cannot
- Since the biomarker committee limits the profile to requirements necessary to achieve the Claim, the Claim does not hold until all those requirements have been met. However, it is considered that some sites might like to get there in multiple steps rather than all at once, so while they are on that pathway to conformance it would be motivating to be able to bestow some recognition of their progress
- A potential pattern would be for each QIBA Profile to identify which Actor(s) would find it easiest to conform and to check conformance possibilities include:
    - Equipment (scanner) Vendors … Scanner
    - Software Vendors … Software
    - Imaging Sites … Scanner + Imaging Protocol + Software + Remaining Checklist Parameters
    - CROs (Clinical Trials) … Participating Site Conformance + Data Analysis
- Stars could be awarded for each actor that passed conformance, e.g.:
    - One Star: Scanner/protocol (this would be valuable for clinical trials)
    - Two Stars: Scanner/protocol + Analysis software
    - Three Starts: Scanner/protocol + Analysis software + all other Actors (radiologist, technologist, etc.)
- To avoid confusion, it would be helpful if the number of stars (3) and the order of the stars were similar across Profiles
- So, a three-star seal fully conforms to the profile and can presume the Claim performance; a one-star seal does not conform, but has taken a meaningful first step that should still be considered helpful and practical

Next Process Cmte Call: Tuesday, January 5, 2021 at 2 p.m. (CT)