QIBA Process Committee Call

Tuesday, October 6, 2020 at 2 pm (CT)

Call Summary

Attendees:			**RSNA Staff:**
Kevin O'Donnell, MASc (Chair)	Nancy Obuchowski, PhD	Daniel Sullivan, MD	Fiona Miller
Michael Boss, PhD (Vice chair)	Nicholas Petrick, PhD	Brian Zimmerman, PhD	Joe Koudelik
			Susan Stanfa

Minimizing Profile Length

- Discussion on application of industry concept, "minimum viable product," to QIBA Profiles, i.e., minimally useful product/Profile to be fielded; feedback would inform future, ongoing iterative product/Profile development
    - The goal is to optimize cost-benefit
    - To accomplish this, a BC would determine the three most important Profile requirements (i.e., "shall statements") and make a convincing case for including additional requirements
    - Suggestion to leverage the diminishing returns curve, i.e., the first few "key" requirements are the most valuable
        - During the Profile-writing process, groups often focus on the scientific benefit without considering the incremental user cost for each requirement, e.g., time, effort, staff support, etc.
        - For some of the later requirements, the cost-benefit may be weak
    - Suggestion to add this topic to Q4 CC agendas and request that one BC from each modality volunteer to shorten its Profile to test the process
        - There may be unique challenges when putting this concept into practice across QIBA groups
        - A better understanding is needed re the reduction of requirements and how this may degrade the claims
        - MR has many requirements in the protocol; if eliminated, results would be negatively impacted
        - Dr. Boss volunteered the DWI Profile because this group is concerned about the length of its Profile
        - The CT image metrics (e.g., resolution, noise, etc.) encapsulate many Profile parameters, but the Advanced Disease Profile was suggested as a possible candidate
            - It was noted that in clinical trial settings, the increased workload of volumetry is not leading to shorter, smaller, or faster trials, indicating that major changes are needed
        - FDG-PET was suggested, however, Dr. Zimmerman noted that the BC is considering rendering this Profile dormant and shifting efforts elsewhere; another NM Profile based on F18 might be a sounder choice
- Discussion needed re: whether significantly reducing Profile lengths is part of the Process Cmte resolution process and it needs to be determined whether QIBA leadership approval is needed to begin this process

Improvement of Biomarker Committee Coordination

- It was suggested that a single, one-hour meeting per month provided an insufficient amount of time for collaboration
- Groups of 3 – 5 core BC members may be formed to meet offline to focus on detailed tasks, e.g., Profile-writing; lead editor to be defined
- Discussion re: updates to the Profile-writing guidelines
    - Recommendation to consider checklist actors early in the development process; there must be alignment between checklists and specifications in the body of a Profile
    - Public comments to be addressed as they are received; progress should not be stalled by waiting until the submission deadline to discuss them

Demonstrate Proof of Value

- The overall goal would be to demonstrate a study that reduced variance, a site that reduced errors, and/or improved outcomes as a result of following the requirements specified in a QIBA Profile
- Suggestion to partner with clinical trials
    - Obtain direct data from clinical trials
    - Use retrospective analysis from trials that have already been completed
    - Consider a direct trial that tests a QIBA Profile; this is how to show that the QIB improves outcomes
- Diagnostic accuracy has an inherent value; biomarker selection criteria should be based on clinical value added
- Consider evaluating the "value statement" during Profile selection/BC approval
    - Obtaining data should be a critical step; it is a critical task during when conducting early groundwork
    - This concept might already be included in the translation/transformational category; specifically asking for the BC proposal to address this question will be considered
    - There is an assumption that the proposed biomarker will be valuable; determine how the assumption should be stated and examined

Next Steps

- Dr. Boss and Mr. O'Donnell to BC coordination guidelines
- Dr. Boss to reference Profile-writing guidelines and work with Mr. O'Donnell to update this text
- CC Membership Structure to be discussed during the Oct. 15 EC meeting; Mr. O'Donnell to draft a change proposal
- The QIBA Wiki will be updated to reflect ballot text revisions
    - "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
    - The issue of conflict of interest for ballots to be revisited

Next Process Cmte Call: Tuesday, October 20, 2020 at 2 pm CT (1st & 3rd weeks of each month)