QIBA Process Committee Call

Tuesday, February 18, 2020 at 3 p.m. CT

Call Summary

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

Biomarker Adoption Steps and Supporting Materials

- Process Cmte members were asked to review sections on conformance testing, record testing and communicating conformance for discussion; detail related to all discussions can be found in the Google Doc
- Step 6: "Communicate Conformance" was reviewed and feedback was provided
- There was discussion on defining and naming the two roles involved with conformance communication
    - "Conformant actor(s)," e.g., products or sites that seek to satisfy the requestor
    - "The interested partner," solicitor of conformance, e.g., sites, core labs, clinical trials, physicians and scientists
    - Facilitator(s), e.g., QIBA (to register conformant products/sites)
    - Discussion re: parties to include in "interested partner" list and reasons conformance might be solicited by each of them

- "What's happening" section:
    - Discussion re: basic or detailed audits and what each would entail as functions of the level of accreditation being done
    - Other considerations were discussed, e.g., sponsor of a clinical trial and their preferences, level of quality needed, how needs may change over time

- Output documents
    - QIBA registered – cataloging self-attestations as a facilitator for convenience
    - Discussion re: assessment results that may be sought for each level of conformance
        - Brief assessment (for basic audits): completed checklist, protocol used, numerical scores e.g., for noise/resolution metrics as stated in Profile, "Scoresheet," e.g. tumor volume worksheet for segmentation
        - Full assessment (for detailed audits): phantom images from device assessments, more detailed software output, logs that indicate staff who have been assessed on knowledge of/adherence to Profile requirements
        - Additional information re: ACR accreditation process may be helpful
        - Core Labs vet incoming site data – e.g., QA, DICOM header checks, PET/CT, depends on stability QIB in question
        - It was noted that Profiles may be referenced for specific, ongoing QA requirements
        - Discussion re: practical frequency (recency) of performing conformance assessments
            - A data-driven determination may be cost-prohibitive to acquire
            - BC feedback needed re: a QIBA assessment cycle; a 3-5 years default was suggested based on QIBs
            - BCs may choose to align with the time sequence and other standard recommendations included in their respective QA Profile sections

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