QIBA Process Committee Meeting
Tuesday, January 3, 2023, at 2 pm (CT)
Meeting Summary

Attendees:			**RSNA Staff:**
Kevin O'Donnell, MASc (Chair)	Timothy Hall, PhD	Nicholas Petrick, PhD	Joe Koudelik
Michael Boss, PhD (Vice Chair)	Nancy Obuchowski, PhD	Daniel Sullivan, MD	Susan Stanfa
Caroline Chung, MD			

Next Steps / Action Items:

Review and Update of Stage 4 Trial Requirements (applicable across modalities)

- Two or more procedurally independent clinical sites (in terms of training, guidelines, policies, etc.) engaging technologists, physicist, and radiologists will be required, though additional sites may be encouraged
- A requirement of one site not involved in Stage 3 feasibility testing was suggested
- At least two scanner vendors to be represented across all participating sites
    - No requirement on the number of scanner models and versions beyond the implicit requirement that two or more vendors would result in two or more models
    - Result of Stage 4 study will include each site listing of the equipment / models tested with a detailed explanation of procedure performed
    - Profile Claim would specify a minimum performance threshold that every vendor should be able to meet
- Proposed baseline requirement of at least four different scanner devices (several of which could be the same vendor/model/version)
    - Depends on the QIB and the nature of model/version-specific variability
    - Core aspect is practicality; BC may modify this requirement based on specific circumstances
    - Profile can refer to stage 4 testing report that describes the scope of testing as the caveat on the Claim
- Sample size to include at least thirty-five test-retest subjects (may have multiple observations within any given subject)
    - If ground truth is known, may be able to work with that instead, but test-retest is the most robust approach
- Balance in sample size between sites and scanners would be optimal
    - As the number of participating sites increases, the impact of subject imbalance among the sites decreases
    - BC might use preliminary data showing fair stability across devices and / or models within a vendor, then can skip the device / model balance
    - Balance / representation across models and devices not required but would be nice to have
- Mr. O'Donnell to work on wording for requirements related to subject removal from the table between scans
    - Both the test scan and re-test scan should independently incorporate normal variation in general details like patient positioning, scanner / patient alignment, etc. and modality-specific details (BC to determine what elements have a repeatability impact and how much practicality impact, and decide what to vary)
    - Duration of time between test-retest will depend upon the modality / technique, e.g., slow-clearing contrast

Next Process Committee Meeting: Tuesday, January 17, 2023, at 2 p.m. CT
Zoom link: https://rsna-org.zoom.us/j/89877175730?pwd=V282c2FPSU1vdDhWejJrSGZYZTVZdz09
Meeting ID: 898 7717 5730 | Passcode: Process