

QIBA Process Committee Meeting
Tuesday, December 6, 2022, at 2 pm (CT)
Meeting Summary

Attendees:

Kevin O'Donnell, MAsc (Chair)
Michael Boss, PhD (Vice Chair)

Timothy Hall, PhD
Nancy Obuchowski, PhD

Nicholas Petrick, PhD
Dan Sullivan, MD

RSNA Staff:

Susan Stanfa

Next Steps / Action Items:

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
- Discussion on whether site familiarity with the Profile through participation in Stage 3 Clinically Feasible (generalizability of feasibility/practicality) would disqualify a site from participating in Stage 4 Claim Confirmed (generalizability of performance)
 - Concerns regarding loss of generalizability and rigor if the same sites participate in both Stages 3 and 4
 - It is important for at least some of the Stage 4 performance data to be collected from sites that are unfamiliar with the conformance requirements
 - The naïve practices are part of the “range of expected performance” expressed in the Claim so it should be represented in the Stage 4 confirmation
 - There was consensus that recruiting two sites not involved in Stage 3 feasibility testing may be too challenging, so a requirement of one naïve site would be an acceptable compromise
- At least two scanner vendors are represented
 - It is acceptable if a given site has only one vendor as long as two vendors are represented across all participating sites
 - To be confirmed that the site guidance for Conformance Statements asks sites to list the equipment / models on which checklist requirements were performed and the Profile Claims would apply to only them
- Elimination of the requirement that scanners from all major vendors providing quantitative imaging for the biomarker being evaluated; there will be no requirement on the number of scanner models and versions beyond the implicit requirement that two or more vendors will result in two or more models
- Baseline requirement of at least four different scanner devices (several of which could be the same vendor/model/version)
 - BC might make a case for relaxing this requirement based on specific circumstances
 - CC would need to review and approve such a deviation
- PC member availability for a meeting on Dec. 20 to be assessed

Next Process Committee Meeting: TBD

Zoom link: <https://rsna-org.zoom.us/j/89877175730?pwd=V282c2FPSU1vdDhWejJrSGZYZTVZdz09>

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