

QIBA Process Committee Meeting
Tuesday, October 4, 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:

Joe Koudelik
Susan Stanfa

Next Steps / Action Items:

Review of Estimates of Precision Guidance Text

- Discussion was continued re: the following *minimum* Stage 4 Trial requirements, which had been intended to be applicable across modalities:
 - Conformance to a Profile is a prerequisite for a Stage 4 trial
 - Two or more independent clinical sites, though additional sites may be encouraged
 - The same clinical sites as used in stage 3 (to assess practicality) may be used in stage 4 (to assess performance)
 - Two or more scanner vendors between the two sites as a baseline requirement, but BCs to decide whether this is sufficient based on their specific situations, e.g., QIB, diversity of models across vendors, etc.
 - Three or more machines (ideally different models)
- To avoid excluding sites, BCs would need to develop a Claim that could be met across several major vendors and software packages
- Demonstrating conformance to Stage 3 or 4 would not be achieved if a Profile is compatible with only one vendor or software package
- In the Profile selection stage, lack of adequate options for scanners or software would indicate that a biomarker may not be a viable candidate for industrialization
- Additional discussion is needed re: how to address the above issues in study design development
- Suggestion that a BC develop a Profile that would be able to be achieved under current circumstances and release an updated version in the future with a Claim that aims for higher performance
- Once a draft has been completed, staff to circulate document for PC review; SC review and approval would be needed prior to posting the document on the QIBA Wiki

Profile Naming Convention

- The [Profile Editions QIBA Wiki page](#) providing details on the naming format, rationale, and usage was reviewed; Mr. O'Donnell to revise in preparation for the next PC meeting on Oct. 18
- Standardized Profile naming is needed to clearly identify which version a user is implementing
- Additional notes and rationale was added to the [Profile Naming Examples Google Sheet](#)
- The PC proposes the following structure: Modality, BC name (abbreviations used as appropriate for audience), anatomy (if applicable), followed by full date of publication; stage name to be added in parentheses when Profile is referenced

Stage 3 Renaming from Technically Confirmed (TC) to Clinically Feasible (CF)

- The Steering Cmte had reviewed and discussed all SC feedback re: the name change before the decision was made
- Most Wiki updates have been made; instances of "formerly named TC" to be removed by the end of 2022

Next Process Committee Meeting: Tuesday, October 18, 2022, at 2 p.m. (CT) [1st & 3rd Tuesdays]

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

Meeting ID: 898 7717 5730

Passcode: Process