

QIBA Process Committee Meeting
Tuesday, August 16, 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
Gudrun Zahlmann, PhD

RSNA Staff:

Joe Koudelik
Susan Stanfa

Next Steps / Action Items:

Review of Estimates of Precision Guidance Text

- Document provides guidance on drafting assessment procedures for Profiles at Stage 3 (Clinically Feasible) and Stage 4 (Claim Confirmed) to test the:
 - Conformance of an actor, and
 - Composite performance of a site (e.g., to compare against the performance described in the Claim itself)
- Discussion focused on Stage 4 Trial Requirements
 - Whom and for what purpose is Stage 4 needs clarity, e.g., for QIBA (Profile development) vs. end-users (conformance)
 - Sites to test whether they meet Profile requirements rather than whether they meet the Claim (while multi-center trials are not required, a test-retest study on a small subset is required)
 - Criteria to be used to distinguish between what needs to be done by the BC to validate that performance is within the Claim conformance range vs. site conformance to the Profile
 - The Process Cmte agreed on the following minimum Stage 4 Trial requirements:
 - Two or more independent clinical sites
 - Two or more scanner vendors between the two sites (increased challenges as more sites are included, e.g., number of IRBs, etc. to be noted)
 - Three or more machines (two copies of the same machine would be acceptable)
 - Collection of test-retest scans on 30-35 human subjects (adding sub hypothesis will increase the subject size)
 - Ways to encourage greater involvement across all vendors were discussed, e.g., vendors may be able to help recruit sites
 - Discussion to be continued during the next meeting on Sept. 6
- Agenda for the next meeting on Sept. 6 can be found on the [Process Cmte page](#) of the QIBA Wiki

Next Process Committee Meeting: Tuesday, September 6, 2022, at 2 p.m. (CT) [1st & 3rd Tuesdays]

Zoom link: <https://rsna-org.zoom.us/j/89877175730?pwd=V282c2FPSU1vdDhWejJrSGZY2TVZdz09>

Meeting ID: 898 7717 5730

Passcode: Process