

QIBA Process Committee Call

Tuesday, April 7, 2020 at 3 pm CT

Call Summary

Attendees:

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

Alexander Guimaraes, MD, PhD
Nicholas Petrick, PhD

Daniel Sullivan, MD
Gudrun Zahlmann, PhD

RSNA Staff:

Joe Koudelik
Susan Stanfa

Updating Profile Stage Requirements

- Discussion re: Profile simplification, conformance via self-attestation and how to involve more people (beyond SC members) in these processes; suggestion to create an ad hoc group
- Several Profiles are approaching the Technically Confirmed Stage, and it is recommended that BCs use the Google-based public [comment resolution spreadsheet template](#)
- When voting on advancement to the Consensus stage, it is requested that BCs provide a copy of their Profile and [comment resolution](#) document with the ballot for voting
- RSNA Staff will post completed comment resolution documents provided by BC Profile authors, on the QIBA wiki
- Prior to a vote for advancement to the Technically Confirmed stage, it is recommended that BCs provide a copy of their field trial (feasibility testing) before an eballot is distributed

Self-Attestation and Registration of Performance Process

- An overview of the conformance process used to test the DWI Profile checklist to achieve self-attestation (SA) conformance was provided:
 - Invicro scanned a phantom at one imaging site, measuring multiple metrics, provided real-world user feedback, and generated a thorough performance report
 - The report was used to create a sample report template to be used for sites that seek SA-credentials; this will facilitate adoption of the DWI Profile and can easily be translated to other Profiles
 - It was noted that Profiles may be too lengthy for real world use, and having a report template (functioning as a checklist with space to provide responses) may be more practical
 - The SIG reviewed the process, checked the report for completeness, received feedback from the DWI BC and met to discuss whether procedures were successfully followed
 - The registration confirmation letter (Conformance Statement) was published on a dedicated QIDW page with restricted access (to QIBA and SIG leadership)
- The process went smoothly for this 1st customer, so the SIG will employ a similar one at the next opportunity
- Volunteer and staff resources were sufficient for this relatively short-term process, but this may not be the case for a more complicated, technical conformance process
- The Conformance Statement template will be circulated and the SIG requests feedback if anything is found to be missing
- Standardized approaches will be established for all Profiles
- The Process Cmte will revisit this topic during its April 21 meeting and will determine next steps for informing the wider QIBA community about the self-attestation process
- For conformance-testing of each Profile, BCs to provide expertise/feedback re: implementation and phantom-imaging and clarity re: what is needed to demonstrate conformance (report/data wise)
- SIG requests input re: conformance criteria applicable the CROs, e.g., what should be reported and what resources are necessary re: staff and SMEs

- Additional text to be added to the [Profile Conformance QIBA Wiki page](#); Dr. Boss to review and add any missing information

Technical Confirmation Process (Challenges) for the DWI BC

- Technical Confirmation should cover the full scope of the Profile.
- It is recommended that each requirement be tried by three sites since experience has shown that site opinions and feedback can vary considerably
- The DWI Profile contains multiple organ-specific Claims; discussion re: how to proceed in a comprehensive way
- Various imaging sites have different anatomical expertise and are unlikely to execute the entire DWI Profile which could leave a coverage gap; which means some of the requirements in the Profile did not go through confirmation of their technical practicality; guidance to be provided to BCs re: creating a plan to determine how many sites need to review each organ system to attain full coverage for Technical Confirmation
- To avoid hindering progress, it was recommended that the DWI BC set a maximum of three participating sites
- The FDG-PET and CT Vol BCs completed technical confirmation by having three sites respond to their checklist and report whether the required steps were feasible; some of the sites did not actually perform the requirements (e.g. phantom scanning), which was not strictly recorded or checked at that time

Meeting the Technical Confirmation Bar

- Mr. O'Donnell stressed that the bar for the Technical Conformance Stage (as documented almost 10 years ago http://qibawiki.rsn.org/index.php/Technical_Confirmation_Process) is for sites to actually try implementing the Profile (read and perform the requirements), not simply review the checklist (the site qualification survey does not assess performance in a real-world situation)
 - This has not been well understood across various biomarker committees
 - The Public Comment stage involves sites reading the profile and providing feedback on the effectiveness, practicality, readability, etc. of the Profile
 - A common problem is that lack of clarity or technical difficulties with a written requirement are not clear until someone actually tries to do what they've read
 - The fundamental purpose of the Technical Confirmation stage is to address that. Other sites that are considering reading and implementing a profile can be confident if they see it is Technically Confirmed that other sites have already done so without significant difficulty, so they likely can too.
 - If three recruited sites find it too big of a hurdle to even read and execute the Profile (or the extracted conformance checklist and procedures), this is already a red flag that the Profile is too difficult
 - With several new committees considering Technical Confirmation, it will be important to make sure they understand the nature of the process.
 - If a Biomarker Committee feels they are not yet ready for sites to actually read and execute the Profile, they may decide to do a second round of Public Comments first, and go for Technical Confirmation at some time in the future.
 - Dr. Zahlmann suggested that sites that participate in the Technical Confirmation process should perhaps be given registered status (self-attestation) as a "carrot" for site participation
 - Mr. O'Donnell agreed it was worth considering, but noted that if the Technical Confirmation feedback results in any changes to the Profile requirements, the site will need to be updated to be accurate in conformance
- FDG-PET Profile attained Technical Confirmation based on the feasibility survey (the definition of the day), but a more rigorous process was recommended to add value to this stage
- The [Profile process](#) and [Profile Stages](#) are described on the QIBA Wiki

Next Steps

- Mr. O'Donnell to draft a comparison table containing pathways for self-attestation vs. certification
 - Steps for each site and actor to be included
 - Table to be circulated prior to the April 21 Process Cmte call, during which it will be discussed

Next Process Cmte Call: Tuesday, April 21, 2020 at 3 pm CT (1st & 3rd weeks of each month)