

QIBA Process Committee Call
Wednesday, March 8, 2017 at 3 PM CT
Call Summary

| Attendees: | | | RSNA Staff: |
|---------------------------------------|------------------------------|-----------------------|--------------------|
| <i>Kevin O'Donnell, MASC (Chair)</i> | Brian Garra, MD | Nancy Obuchowski, PhD | Joe Koudelik |
| <i>Daniel Sullivan, MD (Co-Chair)</i> | Alexander Guimaraes, MD, PhD | Eric Perlman, MD | Susan Weinmann |
| Michael Boss, PhD | Edward Jackson, PhD | Nicholas Petrick, PhD | |

Current Priorities

- Updates to Profile Template
 - Decision made to incorporate a conformance check list as an appendix within the Profile Template

- Conformance process to be made more obvious
 - Timely issue, as QIBA groups are currently raising conformance/process questions
 - A common view of what conformance entails, how it is achieved, what it looks like, how it is documented, etc. is needed
 - Definition of conformance (and how it works) needed
 - Mr. O'Donnell to create strawman and report back to QIBA groups

- Discussion on approach of FDG-PET Claim confirmation study
 - Protocol for Claim-Confirmed state is being developed
 - A multi-center trial to clinically confirm the QIBA FDG-PET/CT Profile to be proposed
 - Five sites to be included
 - One aspect of clinical confirmation is to ensure that the statistical assumptions underlying the claim can be met at multiple clinical sites
 - For the current Profile claims, the statistical assumption is that the within-subject coefficient of variation (wCV) is <12%
 - To be roughly the same number of subjects at each site (balanced design)
 - Discussion of advantages and drawbacks of a multi-center study
 - Multi-center studies result in a larger number of pooled cases, have greater generalizability and are less onerous on any single site, i.e. less cases/site needed
 - More statistical confidence resulting in claim-confirmed
 - Disadvantages are higher possibility of protocol/process variation and more coordination required
 - A targeted confidence of variation interval between 10-12% is needed
 - Discussion on addressing site with outliers
 - Site should have been already able to show that it meets QIBA site standards with phantom when following QIBA Profile (technically-confirmed stage)
 - If outlier is significant, site to be examined to confirm if they are Profile conformant

- If conformant, results will be included in data set
 - If not, issue that is preventing site from being conformant to be identified and addressed
- Multicenter study with pooled data to be recommended approach or best practice for clinically-confirmed stage and incorporated into a “Statistical Requirements for each Profile Stage” document to be drafted
- Revision of “Guidance for Testing Actors’ Conformance with Statistical Assumptions Underlying the Claims” document has begun
 - Conformance with the statistical assumptions to be required for all QIBA stages
- QIBA Profile Drafting Tools
 - Some groups have been using Google docs to collaborate during Profile review process
 - When Word document is transferred into Google, Endnote references are stripped out
 - Suggestion to have formatted references in Word and port to Endnote
 - It was noted that some QIBA members don’t have access to Google docs at work due to security restrictions
 - Amazon Chime was mentioned as an economical, yet effective alternative to WebEx
 - Further discussion to occur on collaboration tools in the future

Next Call: Wednesday, March 22, 2017 at 3 PM