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

Attendees:

Kevin O’Donnell, MASC (Chair)  
Daniel Sullivan, MD (Co-Chair)  
Michael Boss, PhD

RSNA Staff:

Brian Garra, MD  
Alexander Guimaraes, MD, PhD  
Edward Jackson, PhD

Nancy Obuchowski, PhD  
Eric Perlman, MD  
Nicholas Petrick, PhD

Joe Koudelik  
Susan Weinmann

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