

QIBA CT Volumetry Technical Committee (TC) Update Call

28 July 2014 at 11 AM CT

Draft Call Summary

In attendance:

Gregory V. Goldmacher, MD, PhD (Co-Chair)
Edward Jackson, PhD (Guest Speaker)
Paul Kinahan, PhD (Guest Speaker)
Hubert Beaumont, PhD
Andrew Buckler, MS

Rudresh Jarecha, MBBS
John Lu, PhD
Michael McNitt-Gray, PhD
Nancy Obuchowski, PhD
Michael O'Connor, PhD

Kevin O'Donnell, MASc
Eric S. Perlman, MD
Nicholas Petrick, PhD
Daniel Sullivan, MD
Ying Tang, PhD

RSNA:

Joe Koudelik
Julie Lisiecki

Agenda: Discussion with Drs. Jackson and Kinahan regarding Technical Confirmation Phase for the Profile

Discussion:

- Drs. Kinahan and Jackson reported to the group about the respective processes to achieve the technical confirmation phase for their respective Profiles, FDG-PET/CT and DCE-MRI.
- Mr. O'Donnell reviewed the four stages of Profile development:
 - Version for Public Comment
 - Publicly Reviewed Version
 - Technically Confirmed Version
 - Clinically Confirmed Version
- The Technically Confirmed version has been publicly reviewed and is administered within the corresponding QIBA technical committees, moving from paper to practice, in preparation for the next phase: Clinically Confirmed Version
- Criteria for claiming Technical- or Clinically- Confirmed status requires additional discussion by the Steering Cttee

Reference provided by Mr. O'Donnell:

- **Compliance** refers to determining whether a product, person and/or site has met the requirements stated in a Profile and is thus in compliance with the Profile. The requirements are stated in Chapter 3 of the Profile. When requirements are stated in terms of a performance metric, the procedure for assessing performance is documented in Chapter 4 as needed to dictate how to measure your performance so you can see if you passed the requirement.
- Compliance is a check of an actor implementation and is performed by a vendor or radiologist or perhaps some independent inspection body.
- **Technical Confirmation** refers to determining whether a Profile is technically correct, in the sense that some compliant set of actors has been shown to achieve the Profile Claim(s), thus (partially) validating the idea that the stated requirements will result in meeting the Claim(s).
- Technical Confirmation is a check of the Profile document/specification and is performed (currently) by QIBA.
- **Clinical Confirmation** would then be a more robust/deep/accurate next step after Technical Confirmation.

FDG-PET/CT Profile

- FDG-PET/CT had a somewhat evolutionary approach, due to the clinically established status of the FDG-PET, extensive supportive literature, and strong opinions of experts on the team
- Numerous normative "Shall" statements are being translated into a user-friendly checklist, based on the real-world field testing done at three institutions
- Once this checklist is complete, it will be tested on a broader test group within the technical committee
 - If all test sites are able to get the same results, this would be considered technically confirmed

DCE-MRI Profile

- PDF-MRI Tech Cttee is working on revision of 1.0 Profile
- Joint effort with ACRIN 6701 test-retest trial, (*Repeatability Assessment of Quantitative DCE-MRI and DWI: A Multicenter Study of Functional Imaging Standardization in the Prostate**)
 - Investigators are trying to follow the DCE-MRI Profile for site qualification and ongoing QC
 - If at least 3 vendors could run the Profile successfully, would consider it technically confirmed, though a clinical trial would be preferred
- The group is also in the process of creating a checklist

Question re: Phantom use in the process

- DCE-MRI: Phantoms were used for imaging site qualification and ongoing QC
- FDG-PET/ CT: Phantom component will be used for the compliance testing, but the group is not yet at this phase

Future Analysis:

- It was also suggested that some data be sequestered for future analysis from each of the groups

Next steps for CT Volumetry:

- Group to contemplate how CT Volumetry can implement similar procedures for technical confirmation phase
- Consider how to establish a process for clinical confirmation and implementing the Profile for claim compliance results

Next calls for QIBA CT Volumetry:

- Monday, August 4th at 11 am CT – Claim Formulation Working Group
- Monday, August 11th at 11 am CT – Image QA activity