

# QIBA Process Coordinating Committee

March 11, 2015 at 3:00 PM CT

Call Summary

## Attendees:

Kevin O'Donnell, MASC (Chair)  
Daniel Sullivan, MD (Vice-chair)  
Michael Boss, PhD  
Cathy Elsinger, PhD

Brian Garra, MD  
Alexander Guimaraes, MD, PhD  
Edward Jackson, PhD  
Feroze Mohamed, PhD  
Eric Perlman, MD

Nickolas Petrick, PhD

## Staff:

Joe Koudelik  
Susan Weinmann

## General Discussion

Mr. O'Donnell welcomed everyone to the inaugural call of the Process Coordinating Committee. The scope of the Committee (as defined in the charter) is to facilitate the QIBA Coordinating Committees and their profiling activities by defining processes and tools to promote consistent quality work product.

An initial priority is to update the common templates for QIBA documents (Profiles, Protocols, etc.) helping to better align the clinical and technical needs across all Biomarker Committees.

Two kick-off questions were presented to the group:

- What should QIBA compliance (self-attestation) look like?
- How best to converge currently used Profile templates – need to systematically incorporate any Profile revisions being used across all BCs and TFs

Mr. O'Donnell reviewed the current DICOM and IHE compliance procedures/documents for applicability to QIBA needs. The DICOM Conformance Statement is very detailed due to conveying implementation level details and individual scanner specifications. The IHE Integration Statement is a (much simpler/higher level) single page listing the IHE Profiles and Actors supported. It is probably appropriate for QIBA statements to be similar to the IHE approach. It was agreed that instructions and parameters used to confirm conformance to the Profile would be included in the Appendices. These additional operating instructions were deemed critical for proper quantification.

## Compliance for Vendors and Sites

Who should be required to prove compliance was discussed. Both vendors and imaging sites suggested to be held accountable in efforts to claim a scanner "supports the QIBA Profile". Since humans such as technicians and radiologists are included as actors, the question arises over how their conformance would be claimed. Site supervisors could sign-off for their staff, avoiding identifying individuals by name. Although some clinical trial sponsors already provide training, the need for specific q-imaging training or q-certification requirement for technicians was raised.

Two separate compliance forms suggested:

- vendor (manufacturer of equipment)
- site (must comply for all sub-actors and can list specific roles/names of positions)

Once vendor and site prove compliance, auditing would be needed for problematic sites on an ongoing, case-by-case basis (i.e., beyond the self-attestation process).

## Format of the QIBA Compliance Statement

Options = Editions = Levels

It was suggested to avoid the overly-complicated concept of “options”, or multiple compliance levels in QIBA Profiles. A simple-to- fill-out compliance checklist, common across all Profiles, was recommended, with appendices allowing freedom to add clinical and technical comments.

### **Profile Versioning**

Profiles not to include major/minor versioning, but would be published as editions identified by the year of publication, e.g., MR Profile (2015)

**Compliance vs. Conformance** - Whether one term and definition better describes this QIBA process requires more discussion

- Conformance = denotes guidelines to which one chooses to conform
- Compliance = denotes regulations to which one is obliged to comply

### **Next Steps:**

- Profile editors to review their specific Profile format modifications and provide a list of 3-5 modifications for discussion on a future call
- A better way to organize material in the Appendices also needed
- Process CC to host bi-weekly calls to maintain momentum
- Next call to focus on how best to revise the Profile template across all biomarker cmtes