QIBA Process Committee  
Wednesday, December 16, 2015 at 3 PM CT  
Call Summary

Profile Template (Mr. O’Donnell)

- The latest Claims Guidance document is available on the QIBA Wiki at:  
- A discussion ensued on section 3.10 Image Analysis regarding qualitative measurements vs. quantitative measurements
  - Measurements can be qualitative but it needs to be determined whether these are in or out of scope for QIBA Profiles and whether they should be alluded to in the Profile Template
  - BIRADS is numerical but is not quantitative
  - The judgement factor involved in this measurement moves it outside of QIBA’s focus on more measurements with manageable sources of variance
  - A stage score can represent certain “chunked” ranges of a numerical measurement, but if we are evaluating a physical parameter, we should present the continuous variable, not a “chunked” range score or a value with lower granularity/precision
  - The Template and Guidance will remove references to qualitative measurements; none of the current QIBA biomarkers use them
  - If future QIBA work finds a case for such things, they can bring it to the Process Committee for further discussion
  - Updates on the Profile template will be made and a new version will be posted to the QIBA wiki

Cross-sectional vs. Longitudinal Claim Development - Updated Flow Chart (Dr. Obuchowski)

- Additional detail was added to this graphic
- Dr. Obuchowski explained the diagram and the group made suggestions and asked questions
  - Terms and acronyms will be defined based on the Metrology papers
- References will be provided when applicable
- When finalized, the flow chart will be embedded in the Claim Guidance document

**Defined Phase of Profile Development (Dr. Jackson)**
- The idea of elevating the Profile at the Public Review Phase to a “published level” was suggested, since the following Technical and Clinical phases were deemed unclear and logistically difficult to carry-out (i.e., field testing/clinical trials)
- Definition and criteria for both Technical vs. Clinical Confirmation needs clarification, as does how these phases associate/tie-into Profile conformance requirements
- A stage in which the Profile has been shown to be “feasible/practical” but achieving the claim has not yet been demonstrated is being considered
- More discussion on this issue to take place at January 21, 2016 Coordinating Committee Leadership call and at the January 27, 2016 in-person Steering Committee meeting
- Process Committee members were asked to submit talking points for the upcoming discussions

**Next Call:** Wednesday, January 13 at 3 PM CT