QIBA Process Committee Call
Wednesday, February 6, 2017 at 3 PM CT
Call Summary

Attendees:			RSNA Staff:
Kevin O'Donnell, MASc (Chair)	Alexander Guimaraes, MD, PhD	Nancy Obuchowski, PhD	Joe Koudelik
Michael Boss, PhD	Edward Jackson, PhD	Nicholas Petrick, PhD	Julie Lisiecki

Claim Guidance Document Topics Discussed

- Claim development language was reviewed in efforts to guide Profile writers and help them determine minimum statistically-sound performance values
- Linearity: No clear definition of linearity is present in some Profiles; additional guidance is needed
- Who will evaluate conformance reports for all Profiles is yet to be determined
- Statistical assumptions will require validation
- Flow chart for claim development will prove very useful to all biomarker committees (BCs)

Review of Example BC Claims

- Issues with the claims should be highlighted when referring to measurement systems
- Committees may need to complete groundwork to validate general statistical assumptions underlying their Claim language
- It may also be necessary to add requirements and assessment procedures to the Profile so that each site / actor will confirm certain assumptions (e.g. demonstrate the linearity of their bias)

Other issues raised

- How practical are cross-sectional vs. longitudinal claims?
  - Provide examples of how to translate statistical terms into confidence intervals
- Bias *in vivo* is very difficult to confirm; Linearity is also an issue, as it affects cross-sectional claims more than longitudinal ones
- Scientific Liaisons will be asked to serve as "missionaries" to instruct their respective biomarker committees regarding new claim procedures and guidance
  - Communication from BC and CC leaders will be crucial to moving the Profiles forward

Posting the Claim Guidance Document

- Mr. O'Donnell will post the Claim Guidance to the "QIBA Process Committee Work Page," and then to the "Claim Guidance" page on the QIBA wiki

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