QIBA FDG-PET/CT Technical Committee April Update

April 30, 2009
11 AM – 12:30PM CDT
Call Summary

In attendance:
Andrew Buckler, MS (Moderator)
Richard Frank, MD, PhD (TC Co-chair)
Nikhil Bhushan, MBA, MS
Paul E. Christian
Constantine Gatsonis, PhD
John M. Hoffman, MD
Yuying C. Hwang, PhD
Marianne Maffoni
Chuck Nortmann
Eric S. Perlman, MD
Daniel Sullivan, MD
Timothy G. Turkington, PhD
John G. Wolodzko, PhD

RSNA
Fiona Miller
Susan Anderson
Joe Koudelik

Agenda (Mr. Buckler)

- Discussion of Profiling for FDG-PET CT similar to the effort for VolCT.
- Reports from subcommittees, time permitting

FDG-PET-CT Profile efforts

- Discussion of best approach to creating a Profile for FDG-PET before the May 19-20 QIBA meeting
  - Suggestion to create an outline for the PET process first, rather than work on individual components of Profile separately
  - Dr Frank and Mr Buckler to create strawman of Profile Claims for discussion at May 19 QIBA meeting
    - Need a layer between the overarching mission of the Technical Committee, and the granularity of the Subcommittees
- The process, similar to VolCT Profiling efforts, would involve developing new format for existing content with understanding that FDG-PET group may not yet have content for Claims sections
  - There are many similarities between VolCT and FDG-PET
  - Contribution is working towards something more effective than current gold standard
  - Balance between the breadth of Profile and the usefulness of Claims; Profile based on specific clinical context.
  - To create a consistent expectation of bias and variance across centers in trials; define expected performance vs. current gold standard and demonstrate feasibility with current state of hardware and software
  - Scope is for both equipment manufacturers and practitioners in multi-center clinical trials
- Discussion of addressing ROI, accuracy and bias in SUV
  - Repeatability is part of the issue
  - Behavioral and biological variables are also involved; endpoints may vary with each clinical case

- Detail, Claims and Clinical Context mesh together (gear slide from Mr Buckler 'Harmonized Approach for QIBA')
- Acquisition system parameters – what vendors and clinicians in the field need to do to meet Claims performance
- Need to know how variable SUV can be
- Possible approach to organizing Claims:
  - SUV=quantitation
  - SUV change=longitudinal measure/effect
  - SUV tumor response=addresses clinical relevance

Discussion of use of terms 'Bias', 'Variance' and 'Reproducibility'

- Bias=systematic over- or under-estimation
- Variance= a generic term with different components
  - Need to characterize factors that affect variability
- Reproducibility
  - Can be influenced and measured
  - Vendors can use this data
  - Should not be lost – is an important issue for QIBA efforts
- Bias is one component of accuracy but controlling variance is much larger
- Suggestion to use terms 1. Bias, 2. Variance, 3. Reproducibility or simply use Bias and Variance

Proposal for NIBIB Funds (Dr Sullivan)

- Dr Sullivan spearheading preparation of funding proposal for NIBIB for June submission
- Would like suggestions for QIBA efforts that need support
- Dr Frank suggested including a request for funding to build phantom(s) and design software for use across platforms in multi-center trials and offered to develop a workplan to be considered for inclusion

Discussion of FDA

- Important to involve FDA now
- FDA Biomarker Guidance(s) for in-vitro diagnostics and for imaging and overall guidance would be helpful to drive industry but need a defined target, e.g. what are metrics at end of 3-4 years? What is the product?
- Dr Sullivan to speak with Janet Woodcock (FDA)

Subcommittee report: Region of Interest (ROI) Definitions (Dr. Turkington)

- Survey ready for scanner and 3rd party workstation manufacturers; will circulate draft to group for comments
- Dr Turkington will draft an introductory letter over Drs Sullivan and Frank signatures to accompany survey

Next Steps

- Dr Frank and Mr Buckler to create strawman of Profile Claims for discussion at May 19-20 QIBA meeting.
- Suggestions for inclusion in NIBIB proposal should be forwarded to Dr Sullivan
- Dr Turkington will circulate draft survey
- Dr Sullivan to speak with Janet Woodcock (FDA)