QIBA FDG-PET Technical Committee Update Call
Friday, January 21, 2011 at 9 AM CST
Call Summary

In attendance:
Paul Kinahan, PhD (Co-chair)
Richard Frank, MD, PhD (Co-chair)
Ronald Boellaard, PhD
Andrew Buckler, MS
David Clunie, MBBS
Patricia Cole, PhD, MD
Howard Higley, PhD
Blaine Horvath, RT
Yuying Hwang, PhD
Niad Mantri
Dennis Nelson, PhD
Ling Shao, PhD
Timothy Turkington, PhD
Scott Wollenweber, PhD
Jeffrey Yap, PhD
Brian Zimmerman, PhD

RSNA
Joe Koudelik
Julie Lisiecki

Alternating FDG-PET Calls (Dr Kinahan)
- FDG-PET Tech Ctte (i.e. regular business) calls to alternate with FDG-PET Profile Authoring Group every Friday at 9 AM CST
- Each group open to all interested Tech Ctte members

Profile Update (Dr Boellaard)
- First FDG-PET Profile Authoring Group call held Jan 14th with an open agenda
- Pragmatic approach to structuring group discussed
- Open to all interested FDG-PET Tech Ctte members
- Dr Boellaard to collect list of core details for next group call discussion, e.g. key works from previous QIBA meetings and specific items to cover in the Profile
- Dr Kinahan to insert UPICT template headers into the Profile template
- Dr Boellaard to add core details into appropriate sections with Profile template
- Mr Buckler and Mr O'Donnell to help determine how to format basic Claim language based on new material
- Next Profile Authoring Group call (Jan 27th at 12 Noon CST) to continue alignment between Profile and protocol sections

Profile vs protocol (UPICT Template) Mr Buckler
- Cross-comparison between Profiles and protocols discussed
- Existing content in protocols to be incorporated within Profile
- Profile scope is beyond protocol; includes Claims and compliance details
- Writing group requests feedback from full Tech Ctte
- Common sections exist between Profile and protocol; to be merged with authoring software demonstrated by Mr Buckler
- Mr Buckler and O'Donnell key editors helping draft FDG-PET Profile
- Dr Kinahan to define Profile scope and strategize how to handle Profiling process at Jan 28th QIBA Steering Committee f2f in Washington DC
- Profile to leverage content from the protocol (i.e. an extension of the protocol)
    - Including Claims, compliance, and actionable tasks for vendors (e.g. wish list)
- Five Profile Sections
    - I Clinical Context
    - II Claims
    - III Profile Detail

    - IV Compliance Section
    - V Acknowledgements
- Authoring software tool overview by Mr Buckler
    - Protocol (template) assembled for an XML schema; evaluating content made easier where multiple documents can communicate without copy/pasting content, i.e. cross-document sharing possible
    - UPICT Template v2.0 to be in XML format
- Focused efforts needed to define criteria and parameters and actual compliance requests
- Multiple parameters and performance levels allowable

FDA Briefing Document Update (Mr Buckler and Dr Higley)

- Draft document a collaboration between fNIH Biomarkers Consortium and QIBA
- Goal of Briefing Document: Assess data for FDG-PET as a response predictor in cancer therapy and diagnostic development and patient management
- First document of this type for imaging to engage the FDA BQRT (experts in institutional implementation)
- Tech Ctte currently responding to comments received from FDA BQRT specifying their expectations
- Revisiting various components now, making subtle revisions; feedback welcome to Dr Kinahan and Mr Buckler
- Comprehensive executive summary being drafted, as well as background, comparative methodology, knowledge gaps, etc
- All sections could still benefit from feedback and read-through for clarity; work still needed in the Methodology section (pgs 28-49)
- Text content to be broken-out into manageable sections; direct document mark-ups requested by Mr Buckler
- Claim language and structure of Briefing Documents establishes basic Claims
- FDA wants a general Claim; but there are limits to generalizability
- Common elements can be used to argue for a broad approach to biomarker qualification
- Basic Claim language getting concise; need to circulate for group feedback (Version 9); Mr Buckler to circulate
- Need to isolate and focus on FDG-PET Claim statements now
- Drs Kinahan and Frank to assist with document development and preparations for the eventual f2f presentation at FDA
- Expect a six- week review process
- QIBA to submit and analyze datasets; review of data required for Full Data Package needed
- Request data from pharma proposed
    - Need for pharma to donate clinical and pre-clinical image data
- Drug correlation results between animals and human subjects
- Micro-PET study literature and pre-clinical data could be mined

QIBA Contract Funding Update (Dr Kinahan)

- Modality Committees submitted ranked funding proposals to the QIBA Steering Committee for discussion
- Steering Committee meeting f2f Jan 28th in Washington DC

Formation of Clinical Effectiveness Review Committee (Dr Kinahan)

- Use of data demonstrating FDG-PET clinical effectiveness as a biomarker being pursued in some funding proposals
- New group being developed to study how data can be used to (essential)

Next Steps:

- Dr Perlman to provide a UPICT Template (protocol) update
- Dr Kinahan to insert UPICT template headers into the Profile template
- Mr Buckler to discuss Profile and protocol relationships
- Mr Buckler to circulate for group feedback:
    - Claim statement
    - Response to specific FDA BQRT questions
    - Briefing Document
    - Decisions Tree
- Dr Boellaard to add core details into profile template
- Next call scheduled for Friday, Feb 4, at 9 am CST