In attendance:

Richard Frank, MD, PhD (Co-Chair)  
Helen Young, PhD  
Nikhil Bhushan, MBA, MS  
Ronald Boellaard, PhD  
Andrew Buckler, MS  
Lori Kaumans (for Paul Christian)  
Steve Kohlmyer  
Eric Perlman, MD  
Ling Shao, PhD  
Jeffrey Yap, PhD  
Scott Wollenweber, PhD  
Daniel Sullivan, MD  
RSNA  
Susan Anderson, MLS  
Joe Koudelik

General Discussion

- **Mission statement for the FDG-PET/CT Technical Committee**
  - Mission; Foster adoption of…
    - pragmatic and cost effective standards for
    - accurate and reproducible
    - longitudinal
    - quantitation of
    - biologic parameters
    - with clinical relevance
    - and known sigma

- **Understanding of Project Scope**
  - To have vendors deliver products (hard/software) decreasing variability in clinical trials
  - Products to the marketplace decreasing the variance in multi-center trials
  - Optimizing behavior to optimize state-of-the-art in within scope
  - What should be achieved (few standards set here) but not how to achieve
  - Prospective human trials currently outside of QIBA scope (but not to be ignored)

- **Adoption in Marketplace**
  1. Make feasible
  2. User friendliness (Usability)
  3. Workflows

Profiling activity

- **1 - Make Feasible (Claims)**
  - Need to set a minimum claim of what can be achieved
  - Conformance/certification that device complies to specified performance level
  - Defining low levels of performance is within scope
  - Caution that scanner performance issues are difficult to dictate
  - Vendor/user interaction involved; don’t make criteria too strict for vendors; pushback possible
  - PET is very user-interactive and human interaction is difficult to measure
  - Vendors and product users need open discussion
- Need to address multi-center trials with mixed knowledge and skill sets to help keep quality consistent
- Claims developed with all stakeholder input; the strength of QIBA
  - If device is used in a specified way, “x” is achievable
  - “x” will be defined by this technical committee

2 - User Friendliness (Usability)
- Is ‘usability’ needed in the Claims language?
- How to quantify usability objectively?
- How do we measure to this requirement?
- Need to compare results at clinical centers; real-life environments needed
- Tools need development to demonstrate achievement
- Efforts need to lead to improved usability
- Vendors can even specify how their products are to be used
- “Usability” to be incorporated within the PET profile

3 - Workflows
- QIBA is involved with the imaging component of clinical trials
- To simplify usability
- How do we record each step of usability/workflow?
  - e.g. reduce a 100 step process to 5 steps
- First phase: identify the 100 steps
- Second phase: reduce steps (improving usability)

Profiling Process
- Profile process needs specific limitations factored in; setting only a target doesn’t help vendors
- Sources of vendor limitations needed first
  - e.g. de-identifying images in clinical trials
- Also need to inform vendors of our needs
  - e.g. push-button de-ID process
- Pharma/CROs/Academia (i.e. users) have contributed most to the VolCT profile
- Readers (from RadPharm) have provided usability to the VolCT profile
- Dr Eric Perlman kindly offered RadPharm’s assistance with readers for FDG-PET

Moving Forward/Suggestions
- The entire FDG-PET/CT Technical Committee is to talk as one team
  - Effort above subcommittee level needed; working calls of entire group required
  - This needs to be a holistic exercise
- Subcommittee Chairs to post to Wiki, similar process as done by the VolCT TC
  - Need “text” volunteers to draft and post on QIBA Wiki
- Pertinent claims and details need to be fleshed-out
- Next group call to be used to lock sections together

ACTION ITEMS:
- Replace “Requirements” with “Target Specification” in profile text
- Load Dr Boellaard’s protocol on wiki followed by text from Dr Perlman
- Subcommittees to send claims and items to Dr Frank; Dr Frank will compile into one document