In attendance:

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

- o Need to address multi-center trials with mixed knowledge and skill sets to help keep quality consistent
- o 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)**
  - o Is 'usability' needed in the Claims language?
  - o How to quantify usability objectively?
  - o How do we measure to this requirement?
  - o Need to compare results at clinical centers; real-life environments needed
  - o Tools need development to demonstrate achievement
  - o Efforts need to lead to improved usability
  - o Vendors can even specify how their products are to be used
  - o "Usability" to be incorporated within the PET profile

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

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

- **Moving Forward/Suggestions**
  - o 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
  - o Subcommittee Chairs to post to Wiki, similar process as done by the VolCT TC
    - ▪ Need "text" volunteers to draft and post on QIBA Wiki
  - o Pertinent claims and details need to be fleshed-out
  - o 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