QIBA FDG-PET/CT Monthly Update WebEx
March 31, 2009
2:00 PM CDT
Call Summary

In attendance:

Andrew Buckler, MS (Moderator)
Paul E. Christian
Igor Grachev, MD, PhD
Yuying Hwang, PhD
Paul Kinahan, PhD
Marianne Maffoni
Michael Miller, PhD
Eric Perlman, MD
Yuanxin Rong, MD, MPH
John Wolodzko, PhD
Brian Zimmerman, PhD

RSNA
Joe Koudelik

General Discussion

How does Profiling fit into what QIBA is attempting to accomplish?

- Andrew Buckler provided an overview of the profiling activities under QIBA
- Cross pollination of best practices and learning how teams can help each other is the goal; need best ways to work together
- Profiles and associated data is central element that brings stakeholders together – with shared data – allows stakeholders to relate to the whole
- Trying to codify efforts into something more procedural
- Continued focus needed on the FDG-PET/CT Subcommittees concerning:
    - QIBA big picture integration
    - Profile and claims formatting
    - Precursors and specifications

Profiling and Claims

- Profiles to be high-level (broad scope)
- Profile scope determined by three questions:
    - What are all clinical questions being addressed?
    - Capture how FDG-PET/CT understands endpoint involved
    - What is the performance of the current accepted methodology?
- FDG-PET/CT may have similar needs as VolCT and DCE-MRI
- Important to articulate what we are claiming
    - e.g. storage, retrieval, informatics items are also included along with performance at scientific level
- Biopharma needs a less burdensome process to qualify new biomarkers
- Vendors want products – need value
- Draw on a "community proof" as a predicate for usefulness
- Users to specify these products
    - Proven technology
    - Qualified products

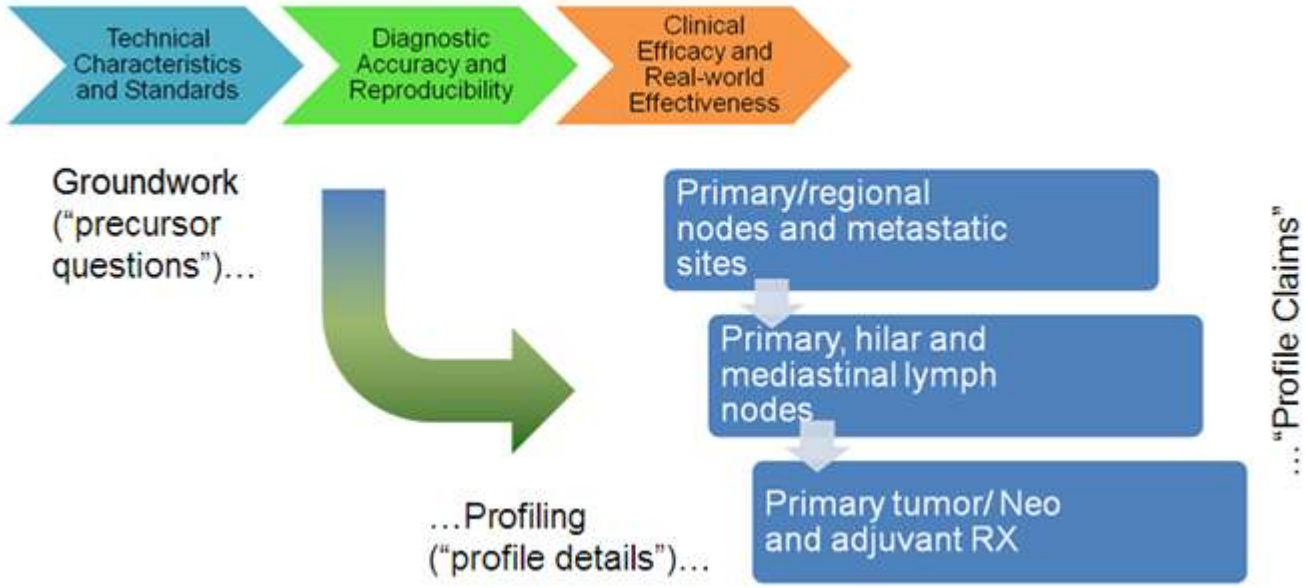
Improving Bias and Variance

- Many quantitative imaging assessment areas can be improved to help with:
    - Reducing patient follow-up/tracking time in clinical trials (i.e. faster response time)
    - Reducing patient enrollment numbers in clinical trials

Groundwork

- Groundwork (details) substantiates claims for biomarkers
- Details: specifications of what is needed to meet claims
    - Details determine the claims made
    - Detail section will be larger than the claims section
- Claims will then be captured in the profile

What is the roadmap for groundwork, retrospective, prospective, and analytical?



(Courtesy of Andrew Buckler, MS)

Spiral vs. Waterfall Model

- Spiral model favored by Volumetric CT Technical Committee
- Does not follow an "A-B-C-D" stepwise order; concurrent projects encouraged
- Start using immediately even while under development
- Development is spurred on by the pressure of the need
- Natural guidance is helpful with this model

FDG-PET/CT Subcommittee Status Update (Drs Kinahan and Perlman)

- Areas that FDG-PET/CT Subcommittees are currently addressing include:
    - Clinical protocols
    - Challenges with DICOM headers, digital reference objects (DRO) and regions of interest (ROI)
    - What is tumor SUV quality?
    - How to identify a change metric for SUV?
    - How tumors generally respond (i.e. no specific tumor types)?
    - Response profiles
- Gathering Information is Step #1
    - What is endpoint we are trying to measure?
    - What is the accepted methodology as perceived in FDG-PET/CT (e.g. RECIST in VolCT)?
    - Which criteria are we trying to improve upon?
    - RECIST is also the "gold standard" criteria for FDG-PET/CT

- Similar considerations across FGD-PET/CT, VolCT and MRI
- What are the rigorous statistical claims to make here?
- Need to know what the vendors can do (what the "ask" is) – what should we be asking for?

Next Steps:

- May 19-20, 2009, QIBA f2f meeting in Chicago
- Distribute slides to the FDG-PET/CT Technical Committee
- Building the technologies for QI in clinical trials – how this will be used in PET needs to be addressed
- What will be done with these technologies once built?
- Public funding may be needed to move the field forward - NIST/NIH funding may be justified