Alternate meanings for Qualification discussed (Dr. Kinahan)

- Site Qualification Process (section 6.1.4) discussed – including parameters and alternate meanings, such as:
  - “Qualification” refers to FDA pathway; suggested use of “compliance” instead
  - Qualification means more testing / research vs. “accreditation” for clinical practice
  - Qualification refers to qualification of the scanner for quantitative purposes
- Separate accreditation from qualification and/or a more general level of usage
  - Qualification: ongoing process of maintaining consistency / accuracy long-term over the course of a trial
  - Qualification: to be approved by body specific research study, or usage, which requires ongoing QA/QC and the collaborative involvement of CROs, ACRIN, CQIE, SNM-CTN, etc.
  - Accreditation: to be approved by body of broad clinical usage, regular ongoing QA/QC, e.g., ACR, CANNL
  - Compliance – is what is necessary to meet the Profile claim
- Sites shall maintain and document accreditation (ACR) or qualification (ACRIN, CQIE, SNM-CTN) status
  - a balance is needed between what is practically achievable while maintaining consistency and quality over time
  - Sites should be accredited or qualified with measurements based on the ACR phantom
  - Goal: for patients to be scanned on different systems with similar results
    - This is important, because even at one site, there can be variance on the same machine!
- Define what threshold levels performance has to achieve, focusing on clinical value
  - Don’t want to make requirements/parameters “too challenging,” where they will not actually help to improve clinical practice, i.e., they cannot and should not be just a lofty “ideal” but rather something usable
- Targeting end of June for Profile to be cleaned up for Public Comment

SNM Meeting (week of June 9-13)
- Group will meet informally, Sunday June 10th, 4:30 pm ET, at the Hotel Fountainbleau, Bleau Bar in Miami Beach to discuss QIBA FDG-PET topics

Next steps:
- Meet at SNM meeting for those available (see above)
- Any comments to Dr. Kinahan, please: Kinahan@uw.edu

Next call: To continue discussion of the Profile at 9 am (CT) June 15th.