

QIBA Executive Committee (EC) Conference-Call Meeting

Thursday, November 19, 2020

10:00 AM (CT)

DRAFT SUMMARY

Participants:

Daniel Sullivan, MD (QIBA Chair)
Alex Guimaraes, MD, PhD (QIBA Vice-chair)
Timothy Hall, PhD (QIBA Vice-chair)
Michael Boss, PhD
Andrew Buckler, MS
Paul Carson, PhD
Patricia Cole, PhD, MD
Caroline Chung, MD
Renee Crucea, MPA
Cathy Elsinger, PhD
J. Brian Fowlkes, PhD

Nandita deSouza, MD
P. David Mozley, MD
James Mulshine, MD
Robert Nordstrom, PhD
Nancy Obuchowski, PhD
Kevin O'Donnell, MASc
Nicholas Petrick, PhD
Annette Schmid, PhD
Anne Smith, PhD
John Sunderland, PhD

Richard Wahl, MD
Gudrun Zahlmann, PhD

Guests:

Ivalina Hristova
Ronald Boellaard, PhD

RSNA Staff:

Fiona Miller
Joe Koudelik
Tori Peoples

Review of 10/15/20 EC Call Summary

The summary approved as submitted.

Dr. Sullivan welcomed EARL representatives to the EC call and brief introduction were made. Collaborations between EANM/EARL and QIBA were a new focus, and this call was to provide information about developing complimentary initiatives among societies. Dr. Zahlmann gave a brief overview to indicate that EARL will be testing a third-party collaboration to get FDG-PET Profiles to Technical Confirmation and in active use.

EARL Update (Ivalina Hristova, BS, CNMT, RT/CT)

- Ronald Boellaard is the Scientific Advisor for the FDG-PET/CT accreditation program
- Scanner and reconstruction introduce variability as indicated in [Dr. Boellaard's presentation](#)
- EARL program is based on EANM guidelines published in 2010 and revised in 2015
- EARL has grown from 11 to 219 centers worldwide with 280 scanners from four manufacturers
- One of the major benefits is that sites can compare SUVs
- Two levels of accreditation are offered:
 - EARL 18F **Standard 1** accreditation – independent QC by expert body
 - accurate, reproducible, and quantitative performance assessment
 - EARL 18F **Standard 2** accreditation -- two quality checks performed:
 - done quarterly using a uniform cylinder with ¹⁸F solution to cross-calibrate scanners
 - done annually using the NEMA body phantom to assess image quality from year to year -- annual accreditation required
- In addition, ⁸⁹Zr PET accreditation has been added as an option with ¹⁸F Standard 1 accreditation
 - 12 sites enrolled with 14 scanners
- Future EARL accreditation efforts include:
 - ⁶⁸Ga: estimated 2021 (WIP)
 - Brain using the 3D Hoffmann Phantom (under evaluation)
 - SPECT (under evaluation)

FDG-PET Profile Update (Gudrun Zahlmann, PhD)

- EARL collaboration is part of QIBA outreach to scientific organizations, commercial entities and accreditation bodies including RadSite, Accumetra and the Clinical Trials Network (CTN)
- Collaborations will help QIBA involve more sites in conformance testing and advance PET SUV as an imaging biomarker
- An MOU has been signed to guide the collaboration
- EARL agreed to engage their accredited sites to help with FDG-PET Profile conformance testing at up to 10 sites
- Collaborating to establish a network of harmonized scanners and sites using the FDG-PET/CT Profile
- Two sites have been identified to-date (at least 10 sites will be needed):
 - University College London Hospital
 - University Hospital Olomouc (Czech Republic)
- Future goal? to develop a proposal to FDA and EMA to implement PET/CT as an imaging biomarker in clinical trials
- QIBA has agreed to promote EARL accreditation program in clinical trials
- QIBA has had some preliminary contact with Median Technologies (CRO)
- Dr. Zahlmann reviewed the process of offering conformance testing for EARL sites

Discussion

Ms. Hristova mentioned that more than ten EARL sites could be engaged to test Profile conformance if deemed necessary. The roll-out of EARL Standard 2 is of high priority, and data analysis may be possible by summer of 2021.

Re: EARL future plans - Dr. Sunderland noted that the CTN/SNNMI have a similar ^{89}Zr PET accreditation program with a comparable number of sites and is already collaborating with EARL. For the proposed brain accreditation program, of some concern was the cost of the required Hoffman brain phantom (\$10k-12k) may make the process somewhat difficult. Ms. Hristova noted that many clinical trial sites in Europe already possess this phantom, so this was not considered an issue.

Dr. Sunderland described the two major areas of EARL accreditation as (1) scanner validation, and (2) guidance on how to perform procedures. Since EANM and QIBA are parallel efforts, it would not be difficult to apply QIBA standards within their programs.

Dr. Zahlmann thanked EARL colleagues for their collaboration and congratulated them for such a good start.

Next QIBA EC T-con Meeting: January 21, 2021 at 10 am CST