QIBA Steering Committee Conference-Call Meeting

Wednesday, April 29, 2020
12:00 PM – 1:30 PM (CT)

Draft Summary

In attendance:

Daniel Sullivan, MD (Chair)
Alex Guimaraes, MD, PhD (Co-chair)
Timothy Hall, PhD (Co-chair)
Michael Boss, PhD
Andrew Buckler, MS
Paul Carson, PhD
Thomas Chenevert, PhD
Patricia Cole, PhD, MD
Therese Cooper, BS, RDMS
Renee Cruea, MPA
Nandita deSouza, MD
Cathy Elsinger, PhD
J. Brian Fowlkes, PhD
Brian Garra, MD
Rudresh Jarecha, MBBS
Emily Lacey, MS
Carolyn Meltzer, MD
P. David Mozley, MD
James Mulshine, MD
Robert Nordstrom, PhD
Nancy Obuchowski, PhD
Kevin O'Donnell, MASc
Mark Rosen, MD, PhD
Annette Schmid, PhD
Lalitha Shankar, MD, PhD
Anne Smith, PhD
John Sunderland, PhD
Gudrun Zahlmann, PhD
Brian Zimmerman, PhD

RSNA Staff:
Angela Colmone, PhD
Fiona Miller
Joe Koudelik
Tori Peoples

Review and Approval of 04/16/2020 Meeting Summary

The meeting summary was approved as distributed. Later edits should be submitted to RSNA staff at qiba@rsna.org

Dr. Sullivan highlighted items from the 4/16 call:

- A draft QIBA members survey will be circulated for SC input in the coming weeks
- Conformance testing and accreditation: Dr. Zahlmann provided an update on current activities
    - Invicro Imaging Center (London) has completed the SA conformance testing process with the DWI Profile and is the first QIBA paying customer
    - Discussions have begun with a second CRO, Imaging Endpoints (IE)
        - IE has expressed a strong interest in QIBA efforts
        - They are interested in engaging in Profile conformance activities at the imaging site and CRO levels
        - IE has identified an opportunity to incorporate the FDG-PET/CT Profile in a clinical trial to begin later this year
        - A third CRO, Parexel, has been contacted to discuss a possible collaboration; future discussion to continue with Dr. Jarecha
        - Clinical care side discussion to continue with RadSite (Dr. Eliot Siegel)
        - EANM and EARL initiatives
            - Discussion with Dr. Boellaard re: opportunities for collaboration between QIBA and EARL have recently started

        - The QIBA FDG-PET/CT Profile might bring value to the EARL initiative
        - Dr. Boellaard will review the FDG-PET/CT checklist and reach out to BC leaders re: a possible collaboration
    - Dr. Sullivan noted that no individual QIBA members site has pursued the SA conformance process with any Profile yet; this will require more discussion
- Considering 90-minute call for the June 18th SC call
    - Original in-person (Annual Meeting) topics re: **value of QIBA to Pharma, CROs, and Cooperative Groups** to be scheduled
- Consider 90-minute call for the August 20th SC call
    - Suggestion made to focus on the **value of QIBA to industry**
    - Staff to poll SC members if a 90-minute call is feasible
    - Reimbursement and payer opinion re: quality milestones to be discussed

Information Dissemination: Publications/Marketing

Relationship of QIBA to AI activities:
Mr. Buckler noted the link between QIBA efforts (i.e., measurement tasks and reproducibility) and AI. QIBA concepts directly affect data quality needed for AI development and testing, but there needs to be a better way to disseminate this relationship to the radiology and computer scientist communities. The ability to have transparent understanding of how an AI tool works, the quantitative dimension, requires buy-in re: units and validation to assure integration and interoperability in workflows. This is a massive opportunity for QIBA to incorporate conformance testing and standardization in AI, based on a metrology framework.

Mr. O'Donnell suggested that the RSNA AI Showcase exhibitors might be a good group to engage and highlight some of the problems that might impinge on full deployment of their tools. AI is vulnerable to poor data quality and QIBA needs to make developers aware of these pitfalls and demonstrate how QIBA could help by addressing measurement variability. The following suggestions were made:

- Key exhibitors from RSNA communication lists could be identified as a starting point for in-person conversations during the annual meeting.
- QIBA leadership could send an email to the AI implementers to start these discussions.
- Consulting with Dr. Erickson on the best approach was suggested due to his large RSNA role in the AI space.
- Dr. Sullivan suggested exploring the idea of a QIBA booth on the AI Showcase floor to promote quantitation and the QIBA efforts.

Dr. Mulshine noted that reimbursement for AI tools will continue to grow but is based on an amorphous assessment process. Many AI developers have little experience working with the FDA. A strategy is needed to tie FDA qualification approaches to reimbursement opportunities since health outcomes and scalability will be critical. Dr. Sullivan reminded the SC that the previously published FDA/CDRH draft product guidance for industry partners gave credit to QIBA for concepts and terminology, which may force manufacturers to think about quantitation and QIBA more seriously.

Dr. Carson noted the need for quantitative data to demonstrate how we could help improve AI results, e.g., demonstrating the degree of accuracy improvement resulting from using QIBA concepts. Dr. Obuchowski indicated that the Metrology Work Group is thinking about this concept and is looking at

the reproducibility of new metrics being used by AI, as well as the use of combined multiple metrics into a final score for variability. Dr. deSouza suggested a focused editorial in *Radiology* highlighting the importance of standardized metrology in AI. Dr. Obuchowski noted that such an editorial could be paired with the Metrology Work Group's overall summary paper currently being drafted.

In addition to AI, Radiomics and Dr. Schwartz' papers on the necessity of harmonization and standardization for Radiomics were discussed.

RSNA Communication Channels – Comments from Angela Colmone, PhD (RSNA)

Dr. Colmone noted that RSNA has several channels of communication available to promote QIBA efforts, e.g., journal editorials, newsletters, social media, etc. The questions QIBA needs to answer are (1) what is the QIBA message? (2) who is the target audience? (3) why is QIBA important to this audience? (4) what is the call to action?

QIBA needs to establish its value to the various audiences. Targeted communications with action responses were deemed most effective. Selecting a designated person to push out social media messages, a common practice in many organizations, was suggested. The person responsible for social media would likely be appointed to the SC.

Outreach to other Organizations - Comments from Renee Cruea, MPA (The Academy)

Ms. Cruea noted the lack of QIBA recognition among members of two Academy councils: Council of Early Career Investigators and the Council of Established Career Investigators. Neither had knowledge of QIBA and the ongoing standardization efforts. She suggested producing QIBA-focused WebEx recordings, or videos, that could be used to better inform these two investigator groups. A "QIBA 101" primer could be disseminated to various patient advocacy groups which are always looking for new collaboration opportunities. Dr. Boss suggested making QIBA presentations to promote QIBA efforts; more discussion needed to determine content. Dr. deSouza suggested offering a small prize for submitted QIBA-oriented work, e.g., posters, abstracts, etc.

Moving Profiles to Stages 3 and 4 – BC Updates

- **US SWS** (to Stage 3)
  Dr. Garra stated one month is needed to address feedback from the public comment phase. Profile is already being followed in existing NIMBLE study, sponsored by FNIH and should allow advancement to Technically Confirmed (Stage 3). To date, no major revisions from Public Comment feedback needed, so the original Profile should be ready soon
- Dr. Garra indicated the participating sites were using the acquisition scheme of the Profile but not following the checklists; this was confirmed by PIs at MGH
- Dr. Zahlmann suggested that the sites should be encouraged to follow the checklist to assess whether they could achieve conformance
    - Dr. Garra indicated that any extra effort by sites might not be tolerated

- Dr. Garra to follow up via e-mail and subsequent calls with PIs to discuss the conformance details, especially if the checklist could be utilized

- **MRE** (to Stage 3)
  Dr. Cole indicated the MRE and PDFF Profiles are also being implemented in the NIMBLE trial which is in the accrual stage at MGH and UCSD. It will take at least one year before data is available. Dr. Obuchowski indicated that they are looking at repeatability and reproducibility for both US SWS and MRE

- **Advanced disease CT Volumetry** (to Stage 4)
  Dr. Jarecha reported that they are reaching out to industry to look for partners to help advance to Claim Confirmed; nothing has materialized to date. Dr. Sullivan indicated that Imaging Endpoints may be interested in implementing the CT Vol Profile which would help validate the claim; follow-up with Imaging Endpoints was needed.

- **Small Lung Nodule CT Volumetry** (to Stage 4)
  Dr. Mulshine noted that the BC was almost done addressing feedback from the Public Comment phase. Waiting from feedback from Dr. Silva in Italy (delayed due to COVID-19). Discussions underway re: advancing to stage 4 being linked to device qualification. Efforts continue with Dr. Obuchowski to get FDA validation re: SLN performance.

- **CT Angiography** (to Stage 2)
  Mr. Buckler reported that a vote to stage 2 is underway. Voting members of CT CC were encouraged to submit their vote asap. There are two principal use cases; coronary and carotid disease with two sites engaged to pursue each use case, but COVID-19 has delayed progress.

- **DWI-MR** (to Stage 3)
  Dr. Boss noted the challenges his BC faced working with four organ systems vs. one. Collaboration continues with Invicro and their imaging site in the UK to get prospective study/test data to support feasibility and claims. Hoping to acquire test/retest data to validate Profile claims. Aim is to advance to Stage 3 by end of 2020.

- **FDG-PET FNIH (to Stage 4)**
  Dr. Sunderland reported that the FNIH Immune Response Imaging Group (IRIG) is contemplating adoption of the FDG-PET/CT Profile in a private-public partnership test/retest trial. The opportunity may exist for a multi-arm study using two novel agents to include the FDG-PET/CT Profile as well. Input from IRIG members show support for pursuing all three: test/retest for FGD-PET, and two novel targeted agents. Further follow-up is needed between FNIH staff, agent companies, and QIBA leadership re: interest to participate.

  Dr. Sunderland noted the BC is drafting a white paper on the importance of test/retest data for FDG-PET and quantitative imaging as a touchstone to get more community support.

- **Amyloid PET (to Stage 3**)
  Dr. Smith noted the major hurdle in completing the DRO. U Washington staff is working to make final DRO modifications.
  a. Resources needed at University of Washington to generate the complete 30 volume set
  b. Once DRO is completed, 2-4 companies/sites to run the DRO process as outlined in the Profile,

give feedback, and BC Team discuss and make any needed changes

Completion of the site feedback questionnaire about ability to perform all needed tasks

a. This is in process (Iowa, WUSTL, and sites in Europe via Adriaan Lammertsma (VU Univ Med Ctr)
b. Once feedback received, BC Team to discuss and make any needed changes

The BC next step is to meet with PIs at U Washington on May 9th and either get a reasonable date to complete the DRO or modify the quality control of the Amyloid Analysis Software without the need for a complete DRO.

Next QIBA Steering Committee T-con: June 18th at 10 AM (CT)
Proposed agenda topic: What is the QIBA value proposition for the drug clinical trial community?