QIBA: Original Goals, Accomplishments, and the Future

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QIBA Update

- What were our goals when QIBA was formed?
- What have we accomplished toward our goals?
- A look forward



Subjective Assessment

"Qualitative radiologic interpretation is like art critique – valuable, but variable."

Dan Sullivan, MD



One approach to reduce variability in biomedical imaging is to extract objective, quantitative data from scans

Goal of the Quantitative Imaging Biomarkers Alliance

In a word: *Reproducibility*

• Estimate and increase the reproducibility of quantitative imaging biomarkers (QIBs) across imaging centers, imaging equipment, participants, and time

QIBA Accomplishments

Have we reached our goals?

Is clinical practice of medical imaging a science

or an art?

Is quantitative imaging thought of as an assay?

Is the confidence interval on an assay considered in decision-making???



QIBA Accomplishments - Metrology

Measurement science applied to quantitative imaging

- Robust statistical framework for:
 - Development of cross-sectional and longitudinal claims
 - Quantitative biomarker technical performance
 - Conformance assessment with profile specifications *what does conformance mean?*
 - Study design for clinical trials using QI biomarkers
 - > Five manuscripts in Statistical Methods for Medical Research
 - Two manuscripts in Radiology
 - > One manuscript in the *Journal of the National Cancer*
- Multi-Parameter Quantitative Imaging Biomarkers (mpQIBs)
 - > Understanding the statistics of the input allows prediction of the statistics of the output
 - > A five-paper series in *Academic Radiology* 2023 Vol. 30 Issue 2



QIBA Accomplishments - Processes

- QIBA Processes Rules for the road for a standards organization
 - Processes for:
 - Criteria and approval process for new Biomarker Committees
 - Guidelines for advancement of Profiles though the Profile Stages
 - Define "conformance"
 - Conflict of Interest policies
 - Voting membership
 - Profile templates ... and more
 - The underlying structure for success
 - QIBA wiki will remain a resource on the web



QIBA Accomplishments - Profiles

• 23 Biomarker Committees → *Develop and maintain Profiles*

At Stage 3:

- 1. CTA
- 2. CT SLN
- 3. CT Volumetry
- 4. MR DWI
- 5. MRE
- 6. PET Amyloid
- 7. PET/CT FDG
- 8. US SWS

At Stage 2:

- 1. CT Lung Density
- 2. MR DCE (2012 version)
- 3. MR DCE (2023 version)...to be wiki posted soon
- 4. MR DSC
- 5. MR MSK
- 6. MR PDFF
- 7. SPECT loflupane (2017 version)
- 8. SPECT Ioflupane (2019 version)
- 9. SPECT/CT Tc99m
- 10. US VF



QIBA Accomplishments - Impact

The rigor of QIBA's processes and profiles attracted collaborators

- QIBA's parallel organizations
 - JRS Japan-QIBA
 - ESR European Imaging Biomarkers Alliance EIBALL
 - National Imaging Facility in Australia (future partner?)
- Partner professional organizations
 - American Institute of Ultrasound in Medicine (AIUM)
 - EIBALL
 - ISMRM
 - SNMMI (future partner?)



QIBA Accomplishments - Impact



Publications

Documents by country or territory

Compare the document counts for up to 15 countries/territories.





QIBA Accomplishments - Impact

The rigor of QIBA's processes and profiles attracted the FDA and others

• QIBA documents were cited by at least 3 clinical guidelines, 2 FDA documents, one think tank document, and one document from a German healthcare agency.

Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions Guidance for Industry and Food and Drug Administration Staff

Document issued on: June 16, 2022.

The draft of this document was issued on April 19, 2019.

For questions about this document, contact <u>RadHealth@fda.hhs.gov</u>.



U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health



Acknowledgements

The Academy and QIBA Announce Inaugural Fellowship Recipients



WASHINGTON, D.C./OAK BROOK, Ill. (Oct. 31, 2022) – The Academy for Radiology & Biomedical Imaging Research (The Academy) and the Quantitative Imaging Biomarkers Alliance (QIBA) announce the recipients of their inaugural Academy Council of Early Career Investigators in Imaging (CECI²) & QIBA Fellowship: Shanshan Jiang, Ph.D., and Ashwin Singh Parihar, M.D. This partnered fellowship will offer these early-career investigators the opportunity to engage with some of our communities' foremost experts in the field of quantitative imaging.



Advancing Innovation in Imaging Science



Dr. Shanshan Jiang



Dr. Ashwin Singh Parihar

Dr. Jiang is a member of the CECI² Class of 2020-21 and an assistant professor of radiology at Johns Hopkins University in Baltimore, Maryland. Her research focuses on developing and applying novel MRI methodologies to neurological diseases.

Dr. Parihar is a member of the CECI² Class of 2022 and an instructor in radiology at the Mallinckrodt Institute of Radiology at the Washington University School of Medicine in St. Louis, Missouri. His research focuses on theranostics, nuclear medicine and oncologic imaging.

Dr. Jiang – MR CC

Dr. Parihar – NM CC

Acknowledgements

- Hundreds of QIBA volunteers
 - Leaders on Many Committees
 - Steering/Executive, Coordinating, Biomarker, Sustainability, Process, Metrology,...
- Hundreds more demonstrating interest in QIBA activities
- Our parallel organizations and professional organizations
 - JQIBA, EIBALL, AIUM, ISMRM, ...
- RSNA/QIBA staff
 - Fiona Miller, Joe Koudelik, Julie Lisiecki, Susan Stanfa, and Tori Peoples



QIBA - Looking Forward

- QIBA needs to continue to grow
 - A diverse set of Profiles and checklists provide templates to ease and speed the development of additional new Profiles
 - QIBA will become more efficient with increasing examples of Profiles
 - More Profiles supporting standardization of QIBs provide more options for users to be involved
- Need to focus on where we can have the greatest impact
 - Do we have the right QIBs in our portfolio?
 - The goal is not to simply have more, but the most compelling QIBs
 - Who are our Profiles intended to serve?

QIBA - Looking Forward

- Quantitative imaging efforts within the RSNA will be led by a new committee "Quantitative Imaging Committee" (QUIC)
- QUIC will be led by Tammie Benzinger and Paul Kinahan
 - Both QIBA participants

Take-home Message?

Prioritize and Incentivize Reproducibility

Thank You

The University of Wisconsin Campus On the shore of Lake Mendota

