

# QIBA Accomplishments



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# The goal for today

- Why was QIBA organized?
- What have we accomplished toward our goals?
- A look forward



# 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 through 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*
- 7 Profiles at Stage 3 (Clinically Feasible)
- 8 Profiles at Stage 2 (Consensus)
- 4 Profiles at Stage 1 (Public Comment)
  - Public comment period closed on all 4

We have 15  
(nearing 19)  
“marketable” Profiles

➤ *MRE Profile blazed a trail with rapid stage advancement, obtaining a CPT code for reimbursement, and qualification process for the FNIB Biomarkers Consortium*

# QIBA Accomplishments - QSIC

## QIBA Sustainability and Implementation Committee

- Led pilot studies of conformance to Profiles
  - In clinical/clinical trials environments
    - Invicro – MRI-DWI
    - European Association of Nuclear Medicine (EANM) Research4Life (EARL) – FDG-PET
    - RadSite – FDG-PET
  - In commercial software conformance services
    - Accumetra – CT Small Lung Nodule measurement
    - CaliberMRI – MRI-DWI

➤ *These conformance studies are a prerequisite to Profile implementation*



# QIBA Accomplishments - Impact

*The rigor of QIBA's processes and profiles attracted collaborators*

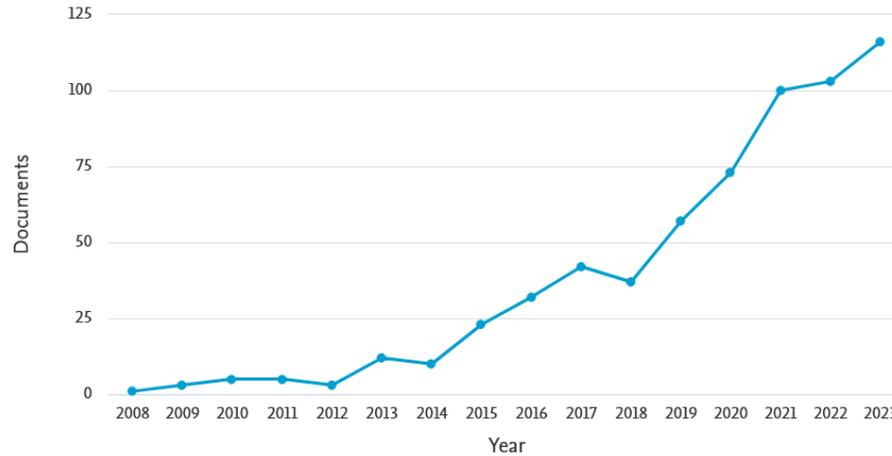
- QIBA's parallel organizations
  - Japan-QIBA
  - European Biomarkers Alliance – EIBALL
  - National Imaging Facility in Australia (future partner?)
- Partner professional organizations
  - American Institute of Ultrasound in Medicine (AIUM)
  - EIBALL
  - ISMRM
  - SNMMI (future partner?)



# QIBA Accomplishments - Impact

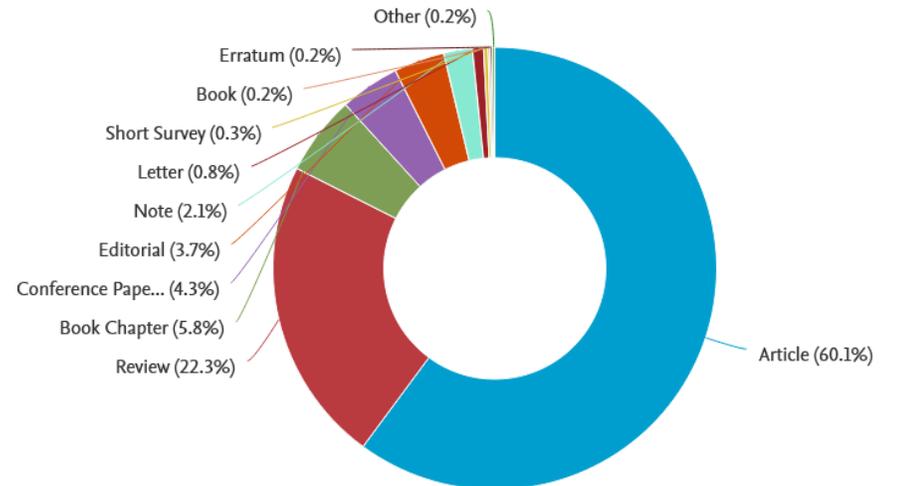
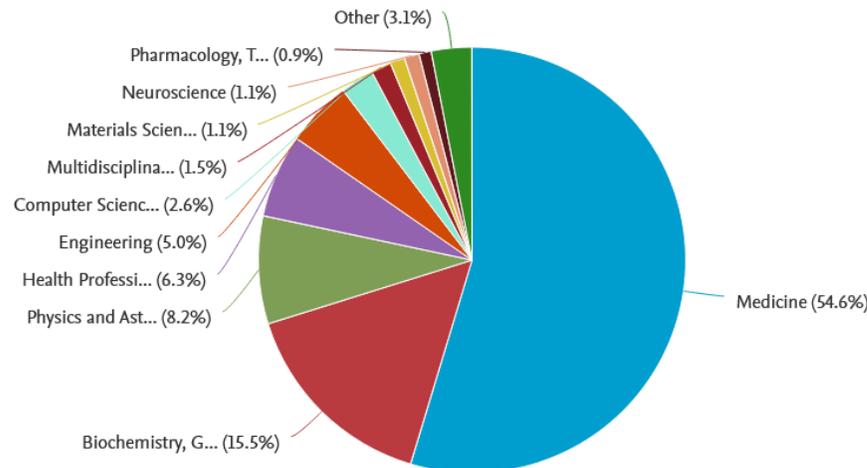
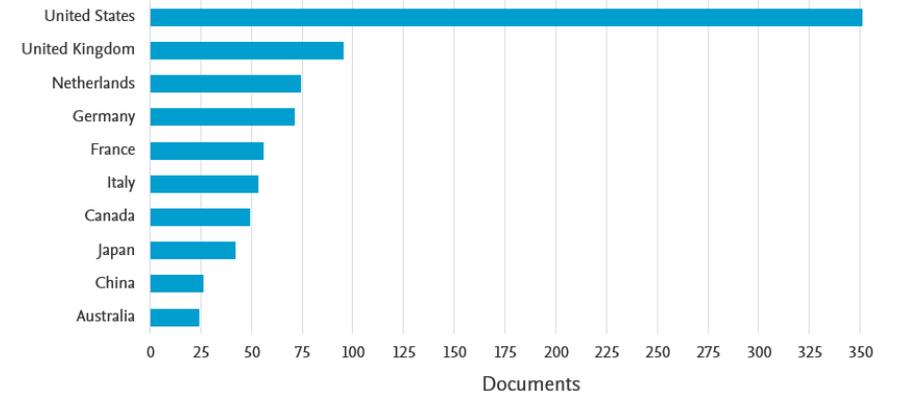
## Publications

Documents by year



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 [RadHealth@fda.hhs.gov](mailto:RadHealth@fda.hhs.gov).



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



# 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



# Where we are headed

## 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 (CECI<sup>2</sup>) & 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.



*Dr. Shanshan Jiang*



*Dr. Ashwin Singh Parihar*

Dr. Jiang – MR CC

Dr. Parihar – NM CC

Dr. Jiang is a member of the CECI<sup>2</sup> 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 CECI<sup>2</sup> 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.



# Where we are headed

- Input from others outside of QIBA
  - Three perspectives
- Guidance going forward
  - #AI4QI
  - #QI4AI

*Thank You*



The University of Wisconsin Campus  
On the shore of Lake Mendota