QIBA External Relations Liaison Report

May 17, 2017
Daniel Sullivan, MD

Topics

• International
  – EIBALL
  – QIBA-Japan

• Domestic
  – Site qualification (NBDA; ACRES; ACR)
  – Profile Dissemination
    • NCTN (NCI-funded Coop Groups)
    • Cancer Moonshot
    • CT Lung Ca Screening
EIBALL
(European Imaging Biomarkers Alliance)
Subcommittee

Siegfried Trattnig
March 2017

Update on Collaboration with QIBA

- EIBALL will work on technical performance characteristics for imaging biomarkers, especially for MR.
- QIBA and EIBALL should collaborate for field tests - i.e., clinical studies to test the clinical validity of the imaging biomarker profiles...
- ...because the bureaucratic hurdles for clinical multicenter trials are somewhat lower in Europe than in the US.
EIBALL – QIBA Collaboration in Technical Development

- EIBALL and QIBA have been interested in establishing, as a collaborative project, an arterial spin labeling (ASL) imaging biomarker committee.
- Proposal approved by QIBA Steering Committee Meeting on February 8, 2017 and by EIBALL in March 2017
- Co-Chairs: Xavier Golay/ Rik Achten
- EIBALL/EIBIR provides administrative, logistical support

Update on Collaboration with EIBIR

EIBIR – EIBALL Joint Initiative since March 2016
- EIBALL is not a legal entity
- EIBIR – operational arm, EIBALL strategic and political arm
- EIBIR provides Staff support (e.g., office facilities)
Collaboration with EORTC

EIBALL to become a platform for the activities of EORTC

- Radiologists (optimal 2) to be represented as imaging liaisons in all steering committees of the EORTC disease-oriented groups to be able to influence new clinical trials and include imaging protocols and imaging biomarker.
- The imaging group has been currently achieving successful integration with the brain, sarcoma and GU groups.
- The group aims to implement more joint working with the GI, Breast, Head and Neck, Radiotherapy and Lung groups.
- About 10 EORTC trials currently have imaging as a primary endpoint.

Site Qualification Process with QIBA

- QIBA and EIBALL are both interested in the development of Quality Assessment of Imaging Centers for IB development and running of clinical multicenter trials with imaging as a possible primary endpoint.
- Quality and risk assessment in imaging will help to improve the quality in clinical trials to get more acceptance from EORTC.
- Active Role of EIBALL/EIBIR?
European Imaging Educational Activities

- Invited talk at the Annual Meeting of the Danish Society for Medical Physicists April 5, 2016 in Odense, Denmark: Lecture on EIBALL
- ESOR course on Imaging Biomarkers (Marti-Bonmati) Valencia, December 12/13, 2016
- ECR 2017 – Joint Session EORTC – ESR (Thursday 16:00-17:30, Room X) «Imaging Biomarker and Education for Multicenter Clinical Oncological Trials”
- Book Project (Springer) “Imaging Biomarker – Development and Clinical Application” (Marti-Bonmati, Alberich-Bayarri)
- EIBALL-EORTC-CRUK article: Implementing Diffusion-weighted MRI for Body Imaging in prospective multicentre trials: current considerations and future perspectives (European Radiology accepted with minor revisions) (N. Desouza)

Future Plans for EIBALL

- Intensify collaboration with EORTC
- Also, focus also on non-oncologic IB such as kidney disease, osteoarthritis, inflammation, lung, etc
- Integrate more European researchers in profile development of QIBA
- Continue Site Qualification Process of Centers in Europe for IB expertise and participation in multicenter trials in collaboration with QIBA and NBDA.
Japan-QIBA
From Japan Radiological Society (JRS)
Shigeki Aoki, Chair of J-QIBA

Special Program about QIBA at the 76th Annual Meeting of the JRS, April 2017:

- Recent trends of QIBA (120 min.)
- Chest CT: Yoshiharu Ohno (Kobe Univ.)
- MRI: Utaro Motosugi (Yamanashi Univ.)
- Nuclear Medicine: Ukihide Tateishi (Tokyo Med and Dental Univ.)
- Industry-academia collaboration: Takashi Ichihara (Fujita Health Univ.)

Japan-QIBA: Future Activities:

**MR**
- Japanese Society of Magnetic Resonance in Medicine (JSMRM) collaborates with J-QIBA;
- There is significant interest in MRE efforts. KAKEN (Japanese Government Agency) assigned a budget of ~$40,000 USD/year to the 3-year J-QIBA project to make a stiffness phantom, which works for both MR and ultrasound elastography.

**NM**
- Active participation in public comment for QIBA DaTScan SPECT profile.
- JSNM invite a QIBA speaker to the Asian Oceania Nuclear Medicine Conference to be held in Yokohama in October 5-7, 2017.
- Developing guidelines for standardization of analysis software.

**CT**
- Developing guidelines for standardization of software.
MR Elastography

KAKEN (Japanese Government 3-year Grant) ~$40,000 to J-QIBA project.
- Stiffness phantom, for both MR and ultrasound elastography.
- Test-retest reproducibility between scanners in different institutions.
- Create large database of stiffness map by MR elastography and histopathological assessment.

- J-QIBA draft Profile Claim

A measured change in hepatic stiffness of 19% or larger indicates that a true change in stiffness has occurred in patient with 95% confidence.

QIBA-Japan NM
(Activities as of Apr/2017)

- FDG-PET Biomarker Center Mitsuaki Tatsumi, MD
  - Profile Field Test: FDG-PET/CT SUV as an Imaging Biomarker for Measuring Response to Cancer Therapy (v1.05): JCOG1305, W-JHS
- PET-Amyloid Biomarker Center Tomohiro Kaneta, MD
- SPECT Biomarker Center Hidehiro Iida, PhD, DSc
  - JSNM software and standardization committee
  - DaT SCAN SPECT multicenter and test-retest reproducibility
  - Quantifying Dopamine Transporters with 123-Iodine labeled Ioflupane in Neurodegenerative Disease (v.0.1) public comment
## Clinical Trials using Standardized PET in Japan

<table>
<thead>
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<th>Study</th>
<th>Scale</th>
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<th>Disease</th>
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<tr>
<td>1. JSCT-NHL10</td>
<td>Domestic</td>
<td>PBSCT, R-CHOP21</td>
<td>DLBCL</td>
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<tr>
<td>2. Phase II</td>
<td>Global</td>
<td>B-Rituximab</td>
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<tr>
<td>3. Phase I/II</td>
<td>Domestic</td>
<td>BCX1777</td>
<td>PTCL</td>
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<tr>
<td>4. Phase II</td>
<td>Global</td>
<td>Bendamustine</td>
<td>B-NHL, MCL</td>
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<td>5. Phase I/II</td>
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<td>SGN-35</td>
<td>CD30+HL, ALCL</td>
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<tr>
<td>6. Phase I/II</td>
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<td>7. Phase II</td>
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<tr>
<td>15. Phase II</td>
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</tbody>
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### J-QIBA CT

- Many Japanese radiologists participating in RSNA-QIBA committees on Lung tumor volumetry, Lung density
- Other CT imaging biomarker possibilities are being considered, such as GFR using CT

Courtesy of Prof. Ichihara, Fujita Health Univ.

Fujita Health University Ichihara Lab.
Japan- QIBA in the Japan Safe Radiology

Japan Safe Radiology

Equipment → Ordering → Scanning → Diagnosis

Proper distribution of medical equipment and radiologists
Clinical Decision Support
Dose Index Registry
Standardization and Optimization J-QIBA
Report Registry
A.I.

Japan Medical Image Database : J-MID

Establishment of Japan Safe Radiology ad hoc committee in June 2016

3 million US Dollar/year project of AMED (Japanese version of NIH) is just started from 2017

J-QIBA is a key for high quality database and A.I.

Database of JRS

A.I., under control of JRS

Appropriate data without domestic and other bias
Feed back
Data for standardization

Appropriateness

J-QIBA
Quantitative Imaging Biomarker

J-QIBA is a key for high quality database and A.I.
Site Qualification

- **NBDA CONVERGENCE CONFERENCE III: IMAGING**
  - July 27-28, 2015
- Initial lack of clarity about the scope of this site qualification process, and determining a coordinating organization
- Overall process and timeline uncertain, pending clarification of organizational support and facilitator/coordinator.
- ACRES (Alliance for Clinical Research Excellence and Safety)

Dissemination of QIABA Profiles

National Clinical Trials Network
1. IROC
2. ECOG-ACRIN
3. Alliance
4. SWOG
5. NRG

Implement QIABA Profiles in clinical trials?
Obtain precision data?
The 8th Edition

Complete Cancer Staging Manual released
October 1, 2016
8th Edition effective with cases diagnosed
January 1, 2018

Basics of TNM Staging System
Imaging in Prostate Cancer

- PubMed search (3/18/17): 12638 results
- Filter for “staging”: 2208 results

Chapter 58: Prostate Cancer

Page 719: Although imaging could one day potentially improve clinical staging accuracy, interobserver reproducibility, issues with patient selection, and contradictory results have limited the utility of imaging in clinical staging, and imaging alone cannot replace DRE as the clinical staging standard. Thus, for local T category assignment, no imaging test is explicitly required.
Although imaging could one day potentially improve clinical staging accuracy, interobserver reproducibility, issues with patient selection, and contradictory results have limited the utility of imaging in clinical staging, and imaging alone cannot replace DRE as the clinical staging standard. Thus, for local T category assignment, no imaging test is explicitly required.

(DRE = digital rectal examination)
Standards for Quantitative Imaging Biomarkers to Advance Research and Outcomes as part of the Cancer Moonshot

By Daniel Sullivan, Duke University Medical Center; Roderic Pettigrew, National Institute of Biomedical Imaging and Bioengineering; Richard Cornmough, National Institute of Standards and Technology and Shadi Marnayshini, National Institute of Biomedical Imaging and Bioengineering

Among the Cancer Moonshot initiative goals are unleashing the power of data and enhancing data sharing. Efforts to facilitate and promote data sharing are crucial to both researchers and clinicians. With improved sharing of datasets, researchers can speed scientific discovery and the development of effective treatments and diagnostics; care providers can improve diagnosis, treatment, and ultimately health outcomes. Medical imaging plays a central role in cancer treatment and research; each year in the United States, about 33 million computed tomography (CT) scans and 1.6 million positron emission tomography (PET) scans are performed. These scans are needed to diagnose cancer, monitor the effects of treatments, and conduct research on cancer and cancer-related therapies. Scans can also assist in...
CT Screening

- Profile released for public comment.
- Active conformance process being discussed/developed with Accumetra.
- Grant application to Prevent Cancer Foundation for non-U.S. conformance activity (~$50K).
- Collaborative discussions at I-ELCAP meetings (Zurich) and IASLC meeting (Oct 2017, Yokohama).
Thank You