



PULSE-ECHO QUANTITATIVE ULTRASOUND

BIOMARKER COMMITTEE

Agenda for Friday, May 7, 2021

11:00am – 12:00pm

Attendees: Ivan Miguel Rosado-Mendez (Co-Chair), Anthony Samir (Co-Chair), Michelle Alexander, Stephane Audiere, Cristel Baiu, Jeffrey Bamber, Richard G. Barr, Paul L. Carson, Anil Chauhan, Guy Cloutier, Aaron Engel, Todd Erpelding, Raul Esquivel, Giovanna Ferraioli, David Fetzer, J. Brian Fowlkes, Jing Gao, Joel Gay, Timothy Hall, Aiguo Han, Jean-Pierre Henry, Viksit Kumar, Roberto Lavarello, Tian Liu, Ted Lynch, Jonathan Mamou, Ravi Managuli, Stephen McAleavey, Andy Milkowski, Kibo Nam, Gary Ng, Juvenal Ormachea, Soufiane Ouhda, Arinc Ozturk, Theodore Pierce, Michelle L. Robbin, Stephen Rosenzweig, Jonathan Rubin, Laurent Sandrin, , Michael Thornton, Theresa Tuthill, Xiaohong Wang, Keith Wear, James Zagzebski, Nancy Obuchowski

AIUM Staff: Kelly Phillips

TOPIC	COMMENTS	ACTION ITEMS
Introduction	Welcome (AS)	
UITC	Update on PEQUS session at UITC symposium (IRM)	
Technical Performance Studies	Overview of guides for designing technical performance studies (IRM)	

Work Groups	Work groups progress reports <ul style="list-style-type: none"> • Attenuation WG (VK, AO, RB, GF) • Backscatter WG (AH, RL, TT) • Sound Speed WG (SR, TP) • Phantom WG (TS, DF) 	
Closing	Closing (AS)	
NEXT CALL	Date: June 4, 2021 Time: 11:00am, EST	

IRM – AIUM/QIBA PEQUS session at UITC

- Authors should have received notification of acceptance
- Session Information
 - Morning (starting around 10am)
 - Either Weds 6/2 or Thurs 6/3
- Order of Talks
 1. Intro to biomarker science – PEQUS leadership
 2. Intro to metrology – Tim Hall
 3. Biomarker talk 1: Attenuation – Attenuation WG
 4. Biomarker talk 2: Sound Speed – Sound speed WG
 5. Biomarker talk 3: Backscatter – Backscatter WG
 6. Phantom talk – Phantom WG

Break

Round table: AIUM LFQ-TF (D. Fetzer) and PEQUS (M.Wang)
- Talks will be pre-recorded (due 5/17)
- More information: <https://uitc-symposium.org/>

IRM – Sources for designing QIB performance analysis tests

- Next steps after drafting claims

- Define strategy for assessment of technical performance to validate the claims
- Goals of phantom study:
 - Validate and refine the claims
 - Address important questions about sources of variability
- IMPORTANT: this is not the technical confirmation stage (after consensus – Stage 2)
- Example of information available – Technical performance test design – how to get started
 - Steps 1-7
- Example of measurement report table from SWS BC phantom study – available on Basecamp

VK – rule of thumb on how many variables can be included?

IRM – depends on which test; reproducibility – no limit

KN – programmed, method of estimation of the parameter, quality of RF data, probe

IRM – WG can address in Step 6

VK – Attenuation WG Summary

- Making claims more specific to phantoms
- Updating the phantom study measurement report sheet
- Submitted revised manuscript to Radiology
- Meeting with BSC WG to finalize the list of questions for vendors related to total attenuation estimation

RB – will have data before next meeting regarding depth dependence in the phantoms and in humans

AS – Status of feedback from Echosens to use a modified phantom for evaluation of CAP

RB – work through it and see what happens; they only do this on a research unit – will do the measurements in Boston – work with the phantom manufacturers – recommend do these measurements last in case phantoms are damaged

LS – CIRS phantom for attenuation measurement – can use commercial system

TL – specifying a membrane that's more fragile than our standard membrane – damage is a concern; if done last, and phantom is damaged, can be placed in a Ziploc with wet paper towel and ship back, it can be repaired

TH – suggest test cylinder with the material, send to Laurent and let him try it on the test rather than the phantom first

TP – Sound Speed WG Summary

- Finalized version 1 of WG Summary – includes details of existing methods and recommendations for phantom study
- Initial claims recommendation posted
- Identified lead authors for review paper – Jeff Bamber and Xiahong Wang
- Vendor Surveys
 - Planned meeting with E-scopics next week
 - Recent request sent to Samsung
- To Do -
 - SoS review paper
 - Position paper
 - UITC abstract presentation preparation
 - Post E-scopics/Samsung vendor surveys to Basecamp

PC – Can all the work groups give a background as to how closely the biomarker is related to liver fat content? So at UITC, people know how relevant they are - Quantitative information should be in each WG abstract/publications

SR – details covered in summary paper that is posted

TT – Backscatter WG Summary

- Keith Wear to assist on Positions Paper
- Discussion on attenuation
 - Question of local or total attenuation has not been asked of vendors
 - How should subcutaneous fat layers be accounted for?
- Meeting with Attenuation Co-chairs this afternoon
 - Drafting questions for vendors
 - Are vendors interesting in compensating for attenuation from intervening tissues?
 - Should summary document include information and statements about attenuation compensation?
- Reviewed original questions for vendors
 - Does anyone have an opinion on dealing with attenuation from the intervening tissue layers?
 - PC – consider use of contrast agents such as multiple lipid agents or bubble destruction
 - GC – would integrating attenuation coefficient increase the variability?

RL – make recommendations/assessments based on algorithms that are implemented or close to being implemented; new methods should not be eligible

AM – FDA will ask to assess to ensure that inserting the fatty layer in the phantom will not adversely affect the estimation; Ask if they compensate for or correct for attenuation value, rather than asking how

AS – what clinical thing would you encounter that would affect variability and incorporate that into the testing?

IRM - Phantom WG Summary

- Start phantom production; timeline
- Begin manuscript on summary document

AS – Early registration for UITC is 5/17

IRM – Reminder was posted on Basecamp about outline on position paper - missing volunteer from Sound Speed WG

AIUM/QIBA PEQUS session at UITC

- Authors should have received notification of acceptance last night
- Session information (TBC)
 - Morning session (starting around 10 am)
 - Either Wednesday June 2nd or Thursday June 3rd
 - Order of talks
 1. Introduction to biomarker science – PEQUS leadership (A. Samir) (12 + 3 mins)
 2. Introduction to metrology – Tim Hall (12 + 3 mins)
 3. Biomarker talk 1: Attenuation – Attenuation working group (12 + 3 mins)
 4. Biomarker talk 2: Sound speed – Sound speed working group (12 + 3 mins)
 5. Biomarker talk 3: Backscatter – Backscatter working group (12 + 3 mins)
 6. Phantom talk – Phantom working group (12 + 3 mins)
- Talks will be pre-recorded (**due May 17th**) and played consecutively, Q&A after 6 talks
- More information about registration & schedule at:

<https://uitc-symposium.org/>



Sources for designing QIB performance analysis tests



PEQUS Biomarker Committee

May 7, 2021

Next steps after drafting claims

- Define strategy for assessment of technical performance to validate the claims
- Goals of phantom study:
 - Validate and refine the claims
 - Address important questions about sources of variability (e.g., depth of ROI)
- **Important: this is not the technical confirmation stage (after consensus (Stage 2))**
- Sources:
 - <https://www.rsna.org/research/quantitative-imaging-biomarkers-alliance/metrology-papers>
- Read Kessler's article for nomenclature
- Example of measurement form from SWS phantom studies provided by Michael Wang on Basecamp

The screenshot shows the RSNA website's 'Metrology papers' page. The page header includes the RSNA logo and navigation links for Membership, Annual Meeting, Journals, Education, Research, Practice Tools, and COVID-19. A search bar and utility links (News, About, Donate, Login) are also present. The main content area features a sidebar with a 'Research' menu and a list of links including 'Metrology papers'. The main text area is titled 'Metrology papers' and contains several paragraphs of text and a list of publications. One publication entry is highlighted with a green box: 'Raunig, DL, et al., Quantitative Imaging Biomarkers: A Review of Statistical Methods for Technical Performance Assessment, Stat Methods Med Res 0962280214537344, first published on June 11, 2014 as doi:10.1177/0962280214537344'. A yellow arrow points from the text 'Read Kessler's article for nomenclature' in the list on the left to this highlighted entry.

Technical performance test design

QIBA Technical Performance Working Group

(Rauing, 2014)

Our current focus



STEP 1: Define the QIB and its relationship with the measurand



STEP 2: Define the study claim or question to be addressed

Hypothesis, general question, statement of bounds on technical performance



STEP 3: Define the experimental unit (Phantoms)



STEP 4: Define the measures of variability to be estimated

Bias, repeatability, intra and inter-site variability, intra and inter-vendor variability, intra- and inter-transducer variability



STEP 5: Specify the elements of the statistical design

Number of appraisers, reference measurement method, range of measurand values, repeatability and reproducibility conditions



STEP 6: Determine the data requirements

Data type and amount, inclusion/exclusion criteria



STEP 7: Define statistical analysis

Hypothesis (superiority, noninferiority, equivalence), estimation bounds

