WISCONSIN
UNIVERSITY OF WISCONSIN-MADISON

Ultrasound QA/QC Workshop
Shear Wave Elastography and Pulse-Echo Quantitative Ultrasound Evaluation

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2021 Annual meeting of the American Association of Physicists in Medicine

July 28th, 2021, 10:30-11:30 ET

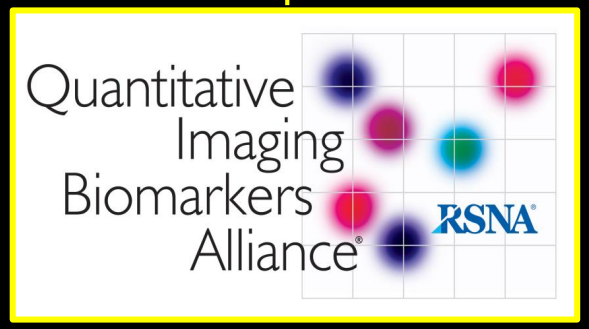
Quantitative Imaging Biomarker

Structural or functional characteristic from tissue measured objectively and derived from an in vivo image as an indicator of a normal biological or pathogenic process or the response to a therapeutic intervention

Technical Performance
(Bias, linearity, precision)

Clinical Performance
Correlation with the biological/pathogenic process or therapeutic response

"Need to define common standards and a cross-disciplinary, systems-based approach to assess performance"

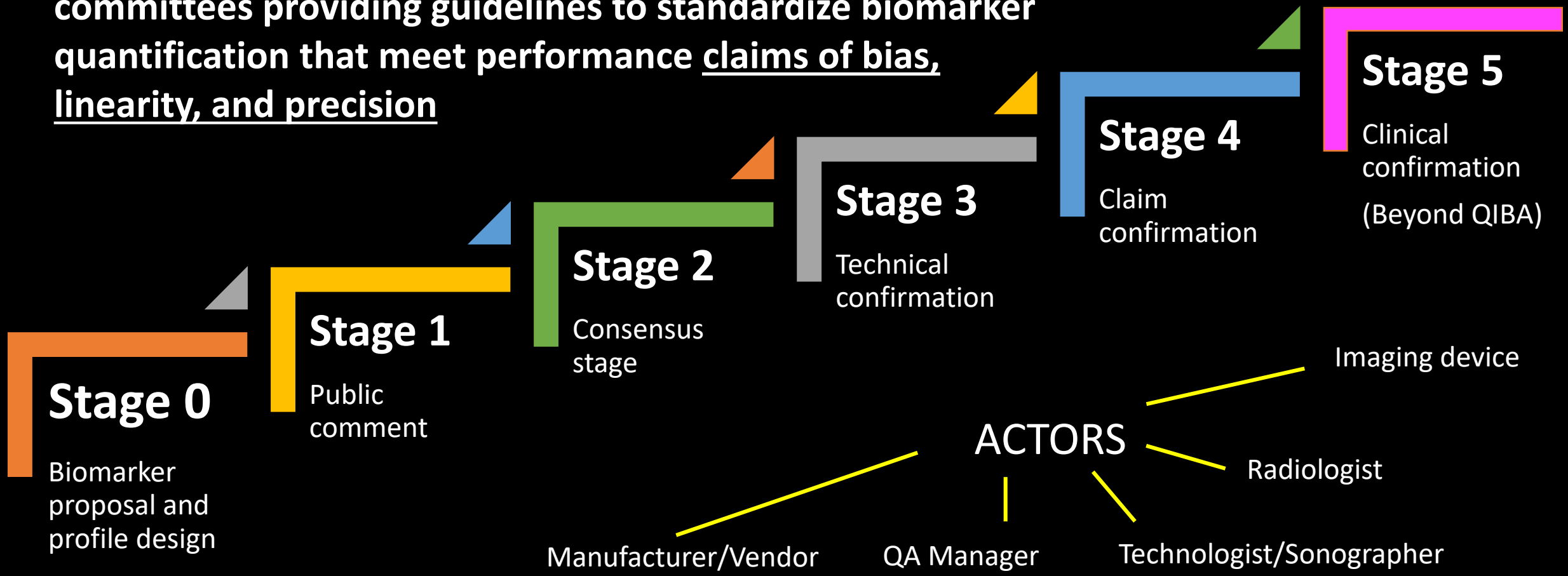


MISSION: Improve the value and practicality of QIBs by reducing variability across devices, patients, and time

Sullivan, *Radiology* 277.3 (2015): 813-825.

The QIBA process

QIBA Profiles: **Documents designed by biomarkers committees providing guidelines to standardize biomarker quantification that meet performance claims of bias, linearity, and precision**



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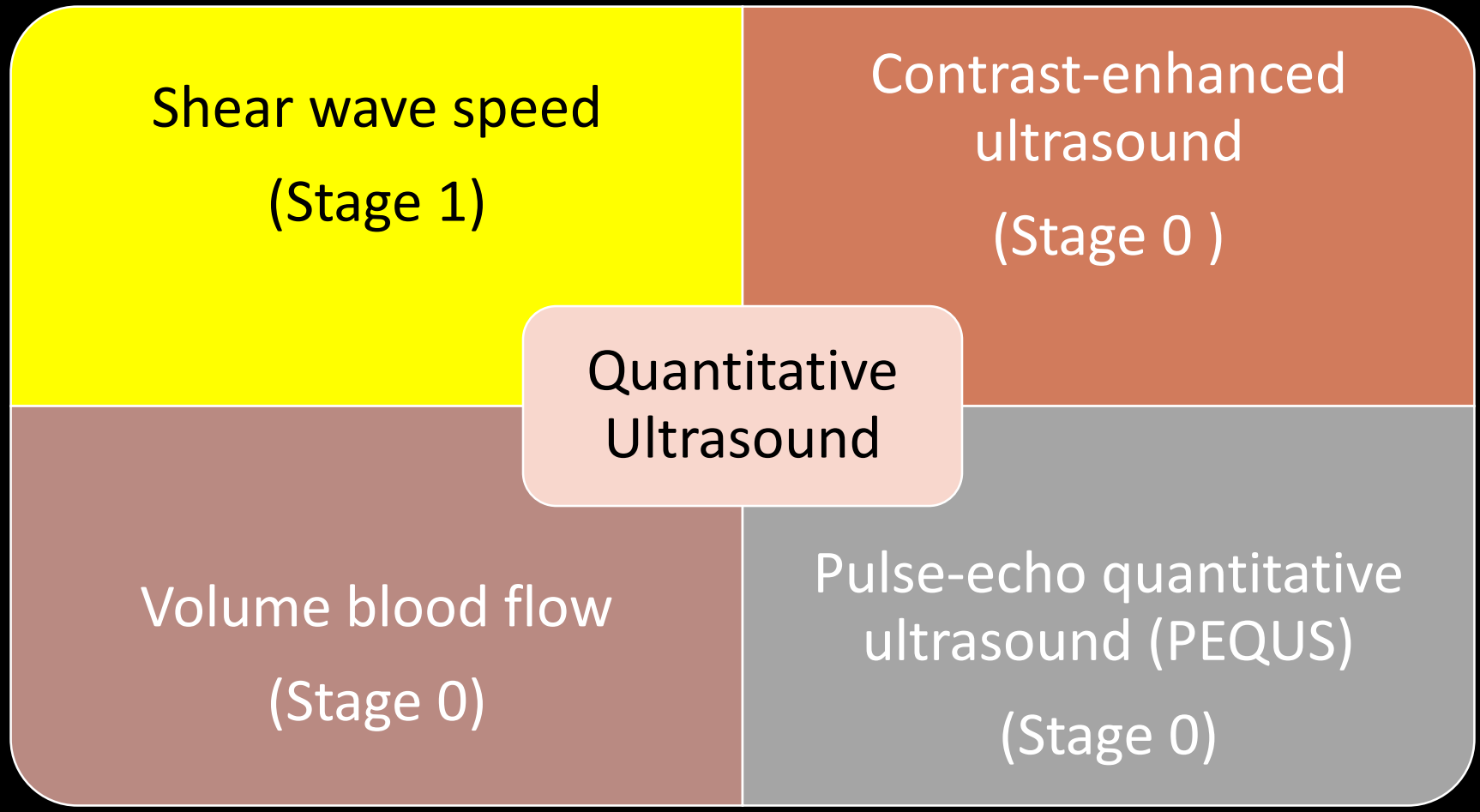
QIBA Ultrasound Biomarker Committees



Shear wave elastography

- Ultrasound based technique used to quantify non-invasively the elasticity (i.e., stiffness) of tissue
- Shear (transverse) waves are induced remotely by acoustic radiation force fields created by long, intense ultrasound (compressional) pulses
- The shear wave speed (SWS) is used as a surrogate of tissue elasticity

$$SWS = \sqrt{\frac{G}{\rho}}$$

$G =$ Shear modulus (kPa)
$\rho =$ mass density (kg/m^3)
Assuming an isotropic, homogeneous, purely elastic solid

QIBA SWS Profile

STATUS: STAGE 1 - PUBLIC COMMENT

Goal: Standardization of SWS quantification as a biomarker for liver fibrosis

Activities for profile implementation

1. Staff Qualification
2. Product validation
3. Pre-delivery
4. Installation
5. Periodic QA
6. Protocol Design
7. Subject selection
8. Subject handling
9. SWS acquisition
10. Imaging QA

Execution and conformance checklists

QIBA SHEAR WAVE SPEED PROFILE EXECUTION CHECKLIST V5.0 Scanner QA Pre & Post Installation

ITEM#	PARAMETER	REQUIREMENT	RESPONSIBILITY/ACTOR	COMPLETED BY [1= Radiologist; 2 = Technologist; 3 = Sonographer; 4= MFR; 5 = QA Manager; 6 = US Scanner]	CONFORMS? [YES, NO, N/A]	NOTES/EXPLANATIONS
3.0	Site Conformance Check					
3.0.2.1	Ultrasound Scanner	Confirm all US scanners conform to Profile	QA Manager			
3.0.2.2	MFR	Confirm manufacturer responsibilities for equipment performance and installation are met	QA Manager			
3.0.2.3	Technologist / Sonographer	Confirm each technologist / sonographer conforms to Profile with training, documented acquistion performance & proper SWS acquistions	QA Manager			
3.0.2.4	Radiologist	Confirm all Radiologists conform to Profile with patient interaction, acquistion performance, and reporting	QA Manager			
3.1	Staff Qualification					
3.1.2.1	Operator Training	Technologist trained and approved for SWS acquisition	Technologist / Sonographer or Radiologist			
3.1.2.2	Operator Qualification	Meets performance requirements on phantoms and subjects	Technologist / Sonographer or Radiologist			Phantom testing-wCV ≤ .05 and/or case review IQR/median ≤ 0.30
3.3	Pre-delivery					
3.3.2.1	Acoustic Output (SWS Mode)	Manufacturer certifies maximum acoustic output levels meets FDA recommendation while operating SWS mode	MFR			Manufacturer specification and certification
3.3.2.2	Acoustic Transmit Focusing	Manufacturer specifies and certifies SWS measurement and Imaging	MFR			
3.3.2.3	SWS Measurement Consistency	Manufacturer confirms SWS Measurement Consistency of the Ultrasound Scanner is within +/- 5%	MFR			See 4.2 Assessment Procedure: SWS Measurement Consistency
3.3.2.4	Ultrasound Imaging Performance	Meets MFR specifications as published in scanner documentation	MFR			See 4.1 Assessment Procedure: Imaging Performance
3.3.2.5	SWS Imaging Performance	Identification and display meets manufacturer specifications listed in Appendix D	MFR			
3.3.2.6	Software verification	Software version equals version specified in QIBA profile (Appendix D)	MFR			
3.3.2.7	Hardware & transducer MFR specified parameters	Ensure the equipment intended for use is listed in Appendix D as a compliant combination of System, Software Revision and Transducer.	MFR			Required Scanner components are present and found in Appendix D; scanner specific instructions
3.4	Installation					
3.4.2.1	Hardware Damage	No physical damage	MFR			
3.4.2.2	Software verification	S/W version equals the version specified in products QIBA Conformance Statement or one listed in Appendix D	QA Manager			
3.4.2.3	SWS Measurement Concordance	Confirm SWS measurements are within +/- 5%	QA Manager			See 4.3 Assessment Procedure: SWS Measurement Concordance
3.5	Periodic Quality Assurance (QA)					
3.5.2.1	US Imaging QA	U/S system QA checks and conform to quality criteria specified in AIUM guidelines	QA manager			On arrival then annually unless potential problem found during operations
3.5.2.2	SWS Measurement Consistency & System QA	Confirms that measurements of SWS on a QIBA elastic phantom using standard instrument settings and acquisition procedures annually, and after any software change are within ± 5% of the values of the Elastic SWS phantom specifications as determined by testing with a Verasonics system	QA manager			Annual testing and testing after any software/hardware change.

Introduction | Pre Acquisition | Subjects & Data Acquisition | Quality Assurance | Profile Conformance-by section | Profile Conformance by Actor

Installation (Acceptance testing)

Parameter	Actor	Requirement
Hardware damage	Manufacturer / clinical staff	No physical damage
Software verification	QA Manager	Shall confirm the software version equals the version specified in the QIBA Conformance Statement or one listed in Appendix D of profile
SWS measurement bias	QA Manager	Shall confirm that **SWS measurement bias is within ±5%**

Periodic QA

Parameter	Actor	Requirement
US Imaging QA	QA Manager	Shall perform standard ultrasound system QA on the ultrasound scanner as specified by AIUM guidelines*
SWS Measurement bias and System QA testing using SWS phantom	QA Manager	Shall confirm that **bias** of measurements of SWS on a QIBA elastic phantom using standard instrument settings and acquisition procedures **annually**, and after any software change, is within **±5% of the expected values in phantoms**
US Imaging and SWS phantom characterization and stability testing	QA Manager	Test for changes in acoustic and elastic properties of phantom, return to manufacturer for reconditioning (or replace) if a weight change of >0.5% has occurred

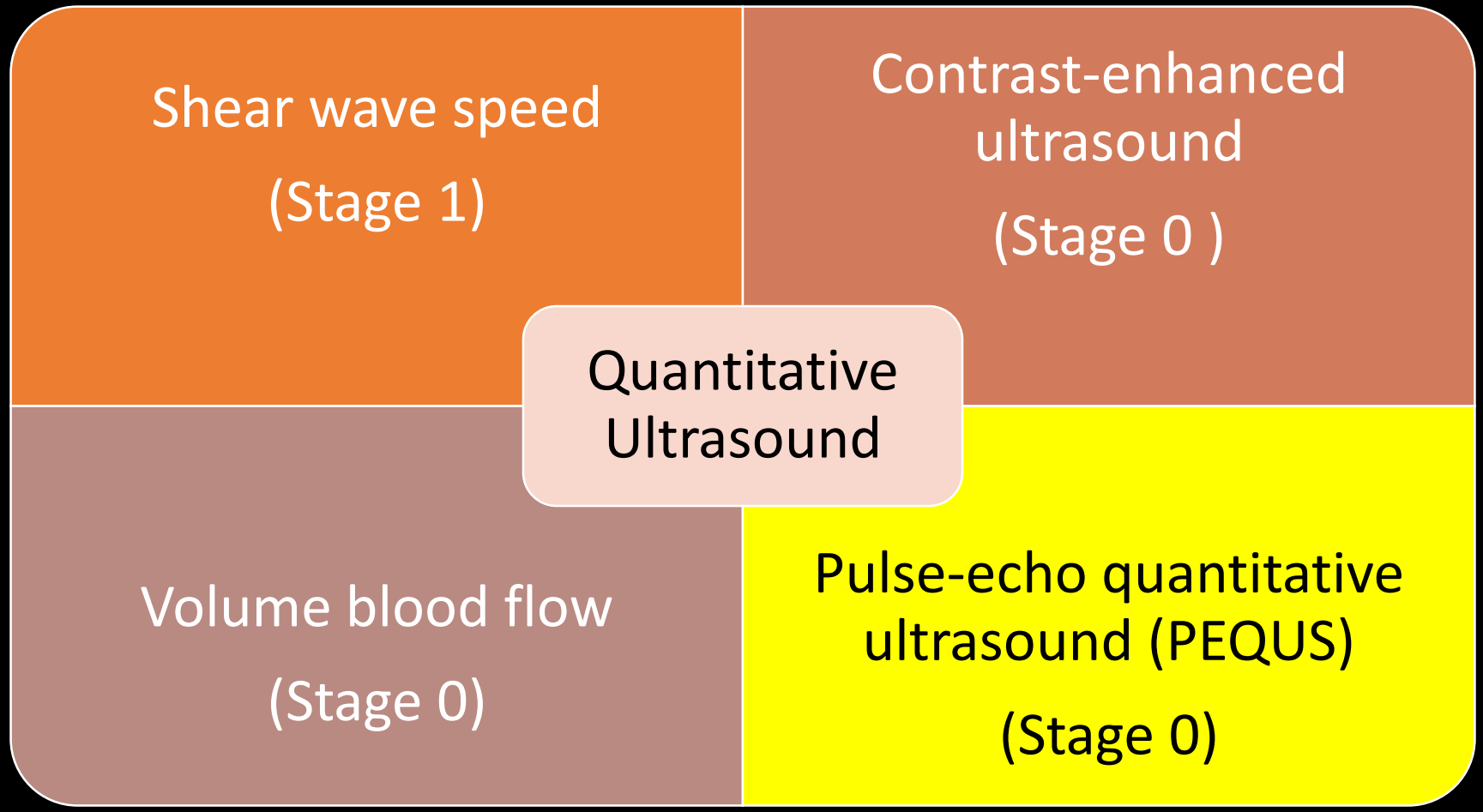
*AIUM Quality Assurance Manual for Gray Scale Ultrasound Scanners,

QA Phantoms

Characteristic	Ultrasound Imaging Phantom	Shear wave speed phantoms
Attenuation (dB/cm/MHz)	0.5±0.1	
Backscatter @ 3MHz (cm^{-1} sr^{-1})	$10^{-4} – 10^{-3}$	
Speed of sound (m/s)	1540±30	1520-1540
Shape	Cylindrical or rectangular	Cylindrical
Height (cm)	15±3	20
Diameter (cm)	12.5±3	12.5
Stiffness	N/A	Normal Liver (0.9-1.2m/s) and F3 fibrotic liver

- Homogeneous phantoms calibrated following protocol for Verasonics research scanner
- The QA manager should arrange for independent verification of phantom characteristics (tolerances provided in the profile)
- Phantoms should be re-weighted every six months; if change larger than 0.5% is observed, phantom should be retested
- SWS measurements must be done at the temperature recommended by phantom manufacturer

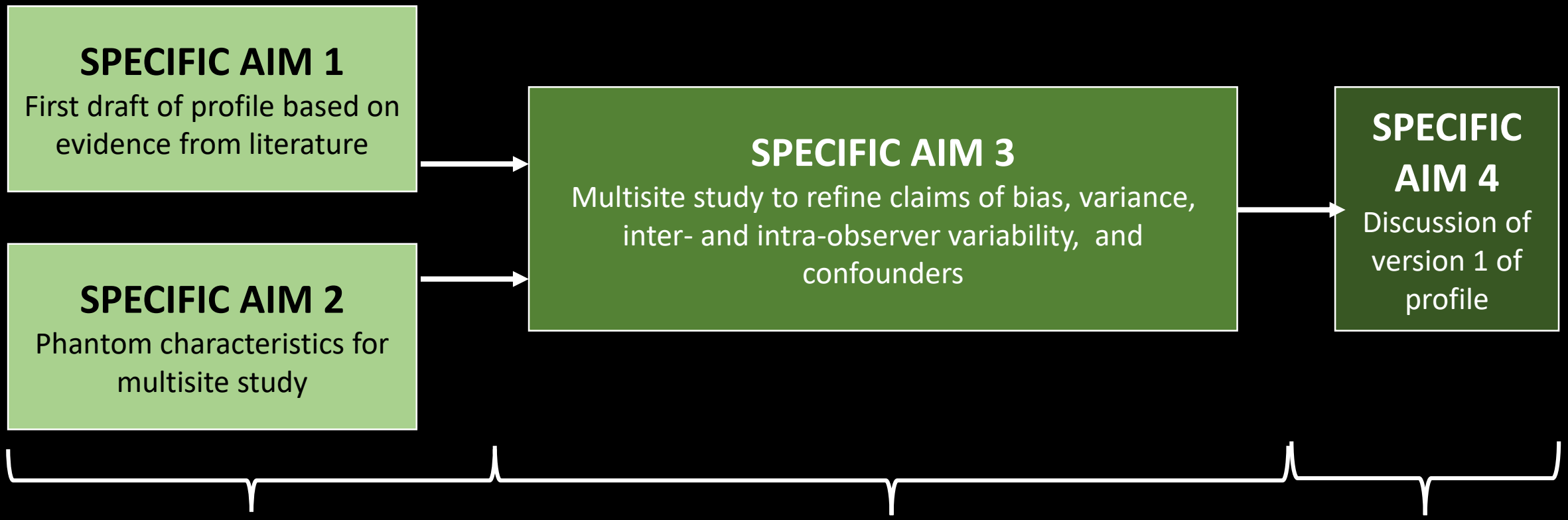
QIBA Ultrasound Biomarker Committees



AIUM/QIBA PEQUS Biomarker Committee

- **Mission:** Reach consensus on how to measure and report pulse-echo quantitative ultrasound (PEQUS) features among manufacturers and under equivalent conditions in the context of assessing liver steatosis
- Motivated by the interest and/or introduction of commercial implementation of PEQUS biomarkers for liver steatosis (fat infiltration) including:
  - ✓Attenuation (fractional loss of ultrasound intensity per unit length)
  - ✓Sound speed (propagation speed of ultrasound waves)
  - ✓Backscatter (fraction of ultrasound intensity scattered back to the transducer)
- Status: **Stage 0 (Est. March 2020, working towards profile)**

AIUM/QIBA PEQUS Timeline



Take home messages

1) Quantitative imaging biomarkers are quantitative features extracted from medical images that are surrogates of structural/functional characteristics of tissue

2) The RSNA QIBA, in collaboration with other organizations such as the AIUM, works towards standardizing their implementation and validation

3) The QIBA Shear Wave Speed biomarker committe has released its profile for public comment, which includes specific QA tasks for acceptance and periodic testing

4) The AIUM/QIBA Pulse-Echo Quantitative Ultrasound (PEQUS) Biomarker Committee is working on the profile to standardize the quantification of acoustic attenuation, sound speed, and backscatter as biomarkers for liver steatosis

Acknowledgments

The PEQUS biomarker committee is supported by

The association for medical ultrasound aium® AMERICAN INSTITUTE OF ULTRASOUND IN MEDICINE

Quantitative Imaging Biomarkers Alliance® RSNA®

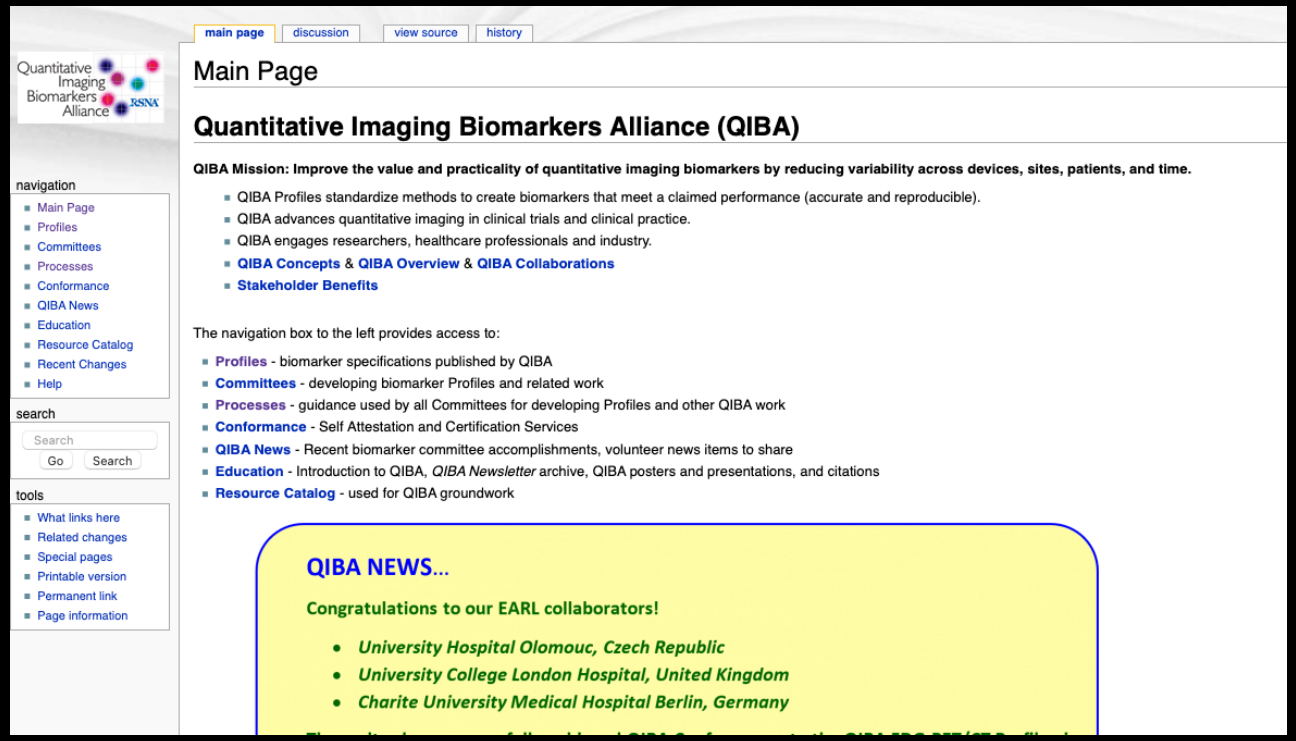
Co-chairs of AIUM/QIBA PEQUS Biomarker Committee

Anthony Samir, MD
Massachusetts General Hospital

Michael Wang, PhD
General Electric

Members of AIUM/QIBA PEQUS Attenuation, Sound Speed, Backscatter and Phantom Working groups

https://qibawiki.rsna.org



Thank you for your attention

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