

# QIBA Process Committee: Overview and Status Update

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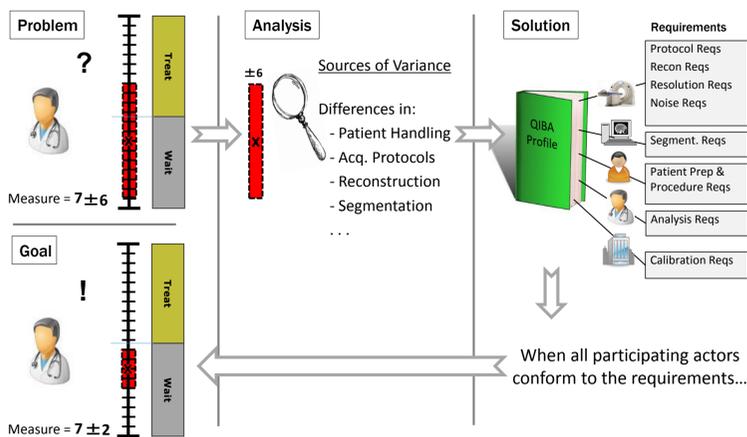
## QIBA Mission

QIBA's mission is to improve the value and practicality of quantitative imaging biomarkers by reducing variability across devices, clinical sites and time.

The initiative engages researchers, healthcare professionals, and the industry to advance the use of imaging biomarkers in clinical trials and clinical practice. This includes:

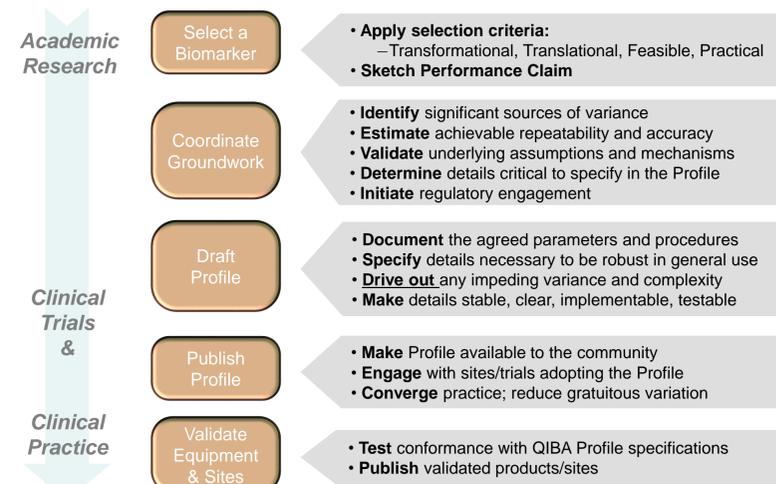
- Collaboration to identify needs, barriers and solutions to create consistent, reliable, valid and achievable quantitative imaging results across imaging platforms, clinical sites, and time.
- Accelerating development and adoption of hardware and software standards to achieve accurate and reproducible quantitative results from imaging methods.

## QIBA – Industrializing Biomarkers



QIBA analyzes sources of variance and bias in the generation of quantitative imaging biomarkers. A QIBA Profile document then places requirements on staff and equipment intended to eliminate or compensate for such sources, or at least quantify their impact.

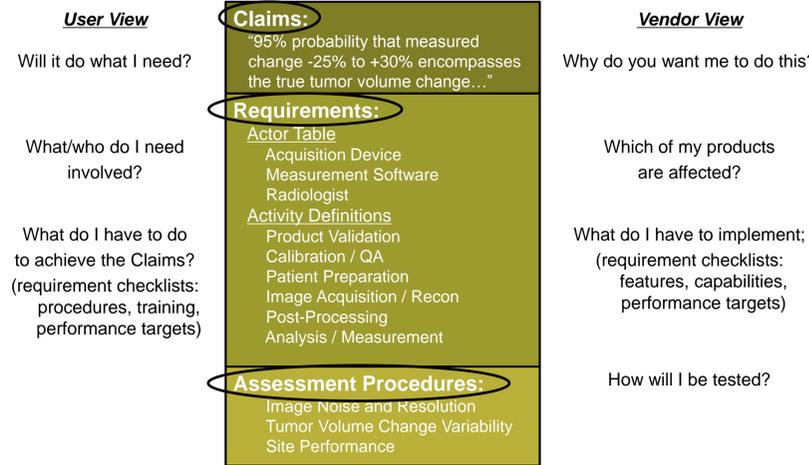
## QIBA Process



## QIBA Profiles

QIBA Profiles are rooted in a biomarker performance Claim. The Profile defines Requirements on how the Activities that contribute to achieving the Claim are performed. Responsibility for each Requirement is assigned to an Actor such as the Acquisition Device, the Radiologist or the Technologist. Some Requirements, such as that on Voxel Noise levels, must be assessed using a specific Assessment Procedure.

### QIBA Profile Structure



### QIBA Profile Stages

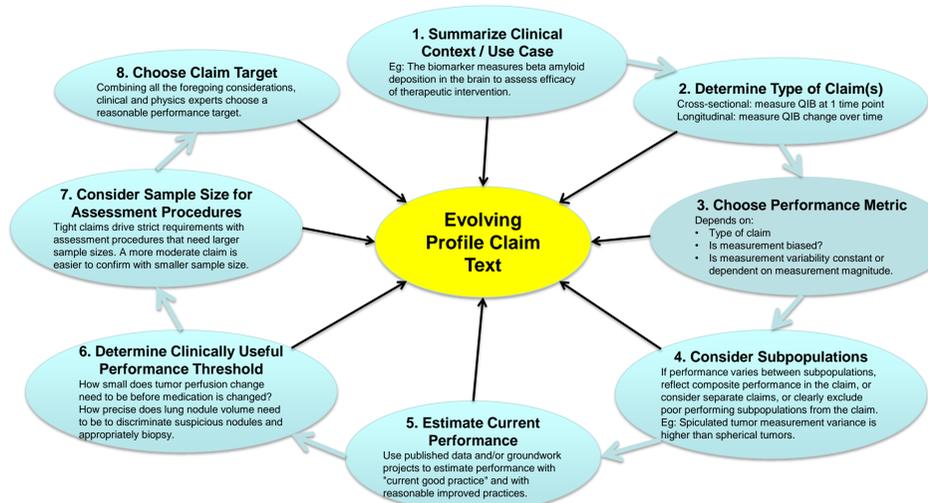
Each QIBA Profile is re-published when it reaches the next developmental Stage. Each Stage represents a progressively higher level of stability of the Profile contents and higher confidence in the Claim. When a given Profile is suitable for their purposes is up to each adopting organization. From the beginning of Profile development it reflects the current best thinking of domain experts. Sites looking for guidance on good practices for generating a given biomarker and easily avoided traps will find QIBA Profiles useful even in their early stages. Clinical Trials and Organizations interested in achieving the specific performance levels in the Claim may wait until later stages.

Stage Name	Stage Meaning	Stage Criteria
<b>Public Comment Draft</b>	Key factors affecting the Claim are described and requirements set for all/most of the factors.	<ul style="list-style-type: none"> <li>• Open issues clearly listed</li> <li>• Some groundwork may be ongoing</li> <li>• Actor requirements clear &amp; justified</li> </ul>
<b>Consensus (Publicly Reviewed)</b>	Consensus reached and ready for trial implementation.	<ul style="list-style-type: none"> <li>• Text reasonably stable</li> <li>• Public Comments addressed</li> <li>• Open issues mostly resolved</li> </ul>
<b>Technically Confirmed</b>	Profile is practical to understand and implement.	<ul style="list-style-type: none"> <li>• Text stable</li> <li>• Open issues resolved</li> <li>• Procedures implemented at test site</li> </ul>
<b>Claim Confirmed</b>	Claimed performance can be achieved.	<ul style="list-style-type: none"> <li>• Performance measured at test site</li> <li>• Profile Claims achieved</li> </ul>
<b>Clinically Confirmed</b>	Claimed performance will typically be achieved.	<ul style="list-style-type: none"> <li>• Profile Claims achieved in clinical use at multiple sites</li> <li>• Note: QIBA doesn't currently evaluate or coordinate transition to this stage</li> </ul>

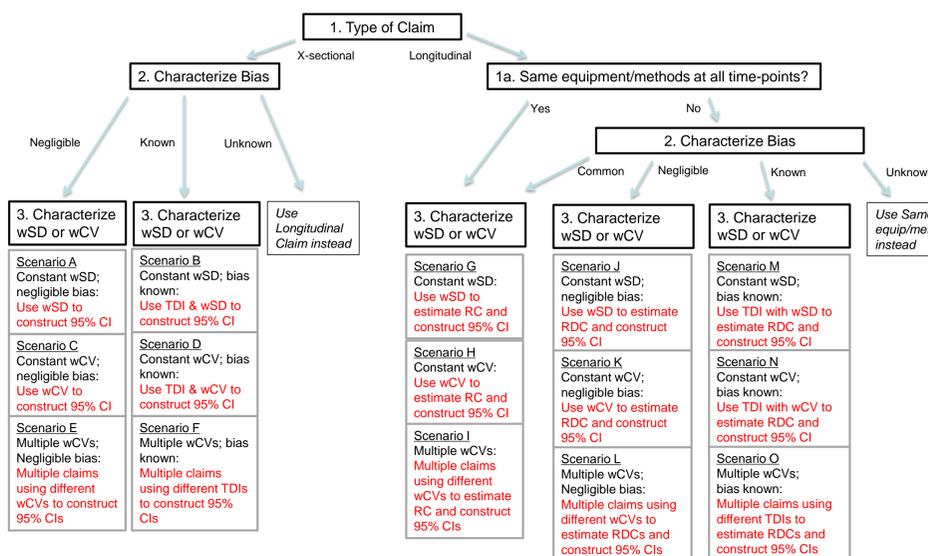
## QIBA Profile Claims

The Claim in a QIBA Profile is both the quantitative performance that results from conforming to the Profile and also the root of all the Profile Requirements. The form of the Claim text evolves as the Profile is developed. It needs to support the clinical context and the use case for the biomarker. It needs to reflect the investigative groundwork. It should target a level of performance that is practically achievable by imaging sites with reasonable equipment and procedures, but is also high enough to be clinically useful. It is also affected by the types of research data available and the ability to perform assessment procedures and other validations.

### Evolution of a QIBA Profile Claim

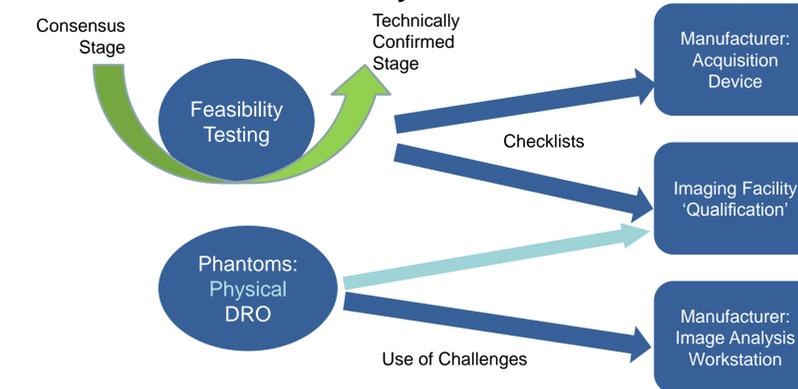


### QIBA Profile Claim Selection Flowchart



## 2016 Status

### Toward Conformance: Grounded in Practicality



### Current Examples of QIBA Profile Claims

**FDG-PET/CT for Tumor Evaluation :**  
Tumor glycolytic activity (SUV<sub>max</sub>) measurements have a within-subject coefficient of variation of 10-12%.

**CT Tumor Volumetry :**  
A true change in tumor volume occurred with 95% confidence if measured change is > 24% / 29% / 39% respectively for tumors with initial diameters of 50-100 / 35-49 / 10-34 mm.

**DCE-MRI for Tumor Response :**  
Microvascular property (K<sup>trans</sup> & IAUGC<sub>BN</sub>) measurements have a within-subject coefficient of variation of 20% from 1.5T DCE-MRI using low molecular weight extracellular gadolinium-based contrast.

**US Shearwave Speed (SWS) for Liver Fibrosis :**  
For a measured change in shear wave speed of (Y<sub>2</sub>-Y<sub>1</sub>), a 95% confidence interval for the true change is (Y<sub>2</sub>-Y<sub>1</sub>) ± 1.96 × [(Y<sub>1</sub> × 0.05)<sup>2</sup> + (Y<sub>2</sub> × 0.05)<sup>2</sup>]<sup>1/2</sup>

**DWI-MRI for Tumor Tissue Characterization :**  
A measured change in the apparent diffusion coefficient (ADC) of a brain lesion of 11% or larger indicates that a true change has occurred with 95% confidence.

**CT Lung Density :**  
Without lung VA, an increase in RA -950 of at least 3.7%, or a decrease in Perc15 of at least 18 HU, is required for detection of an increase in the extent of emphysema with 95% confidence.

\* Some claims have been paraphrased/simplified

qidw.rsna.org

Quantitative Imaging Data Warehouse (QIDW)

The QIDW is an open image archive, built upon the existing open-source Research Data and Analysis Platform, and managed by the QIBA. The archive supports both conventional needs for basic research (raw acquisition images and processing outputs) and secondary analysis of clinical and epidemiological data. The archive is hosted at the University of Wisconsin-Madison, under contract to the National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, Department of Health and Human Services, under contract to the contractor QIDW-C. Development of all data and software for the QIDW is managed by the QIDW-C team, which is led by the QIDW-C Director, who is also the QIDW-C Project Manager.

The QIDW is a public resource and is available to all QIBA members. The QIDW is a public resource and is available to all QIBA members. The QIDW is a public resource and is available to all QIBA members.

qibawiki.rsna.org

Main Page

Quantitative Imaging Biomarkers Alliance (QIBA)

QIBA Mission: Improve the value and practicality of quantitative imaging biomarkers by reducing variability across devices, clinical sites and time.

QIBA Profiles: Standardize quantitative imaging biomarkers to ensure consistency in data collection, analysis and reporting.

QIBA Activities: Collaborate on quantitative imaging biomarkers in clinical trials and clinical practice.

QIBA Engagement: Engage researchers, healthcare professionals, and industry.

QIBA Governance: Govern the QIBA through a representative structure.

QIBA Membership: Join the QIBA today.

QIBA Contact: Contact us for more information.