QIBA Process and Status Update

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QIBA Process

QIBA Mission

QIBA Mission is to improve the validity and reproducibility of quantitative imaging biomarkers by reducing variability and increasing accuracy of clinical use.

The initiative engages researchers, healthcare professionals, and the industry to advance the use of imaging biomarkers and to make the following contributions:

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

QIBA Profiles

QIBA Profiles are a biomarker performance claim. The Profile defines requirements on how the activities that contribute to achieving the claims are performed. Responsibility for each Requirement is assigned to an Actor, such as the Acquisition Device, the Radiologist or the Radiological Society. Key Requirements that are based on User Needs level, must be assessed using a specific Assessment Procedure.

QIBA Profiles are used by vendors to describe the characteristics of their products and by clinicians to evaluate the performance of their imaging systems.

QIBA Profiles are also used to support clinical trials and regulatory submissions. They provide a framework for comparing the performance of different imaging systems and for evaluating the impact of technical and clinical factors on performance.

QIBA Profiles Claims

QIBA Profile Claims are a statement of the quantitative performance that results from conforming to the Profile and also the cost of the Profile requirements. The claim is a product that evolves as the Profile is developed. It needs to support the clinical need and the use case for the biomarker. It needs to reflect the investigational and clinical need, it should target a level of performance that is practically achievable by change sites with reasonable equipment and support, but at high enough levels to be clinically useful.

QIBA Profile Claims are achieved in clinical use and validated by participating sites with reasonable equipment and support.

QIBA Process Stages

Each QIBA Profile is re-published when it reaches the next development stage. Each stage represents a progressive level of stability of the Profile contents and higher confidence in the Claim. When a Profile is first published, stakeholders contribute to the development of the Profile by meeting, discussing and voting on a draft version of a Profile Claim. The Profile Stage of Development reflects the current best thinking of domain experts. It is used as a good practice for generating a quantitative agreement among interested stakeholders.

QIBA Profile Stages

1. Type of Claim
2. Characterize Bias
3. Characterize Variability
4. Define Requirements
5. Test Requirements
6. Converge
7. Profile Claims achieved in clinical use
8. Profile validated
9. Profile available to the community
10. Profile Conformance

QIBA Profile Structure

QIBA Profile Structure is a document that includes the requirements for the Profile and details the outcomes of the assessment process.

QIBA Profile Structure includes:

- User Needs and Requirements
- Assessment Procedure
- Profile Structure
- Profile Content
- Profile Claim
- Profile Consolidation
- Profile Validation
- Profile Conformance

QIBA Profile Selection Flowchart

QIBA Profile Selection Flowchart is a diagram that illustrates the process of selecting a QIBA Profile that meets the user needs and requirements.

QIBA Profile Selection Flowchart includes:

- Select a Profile
- Choose the Requirements
- Evaluate the Profiles
- Select the Profile
- Implement the Profile

QIBA Profile Selection Flowchart is used by clinicians to evaluate the performance of different imaging systems and for evaluating the impact of technical and clinical factors on performance.

QIBA Profile Selection Flowchart is also used to support clinical trials and regulatory submissions. It provides a framework for comparing the performance of different imaging systems and for evaluating the impact of technical and clinical factors on performance.

QIBA Profile Selection Flowchart is achieved in clinical use and validated by participating sites with reasonable equipment and support.

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QIBA 2016 Status

Toward Conformance: Grounded in Practicability

QIBA 2016 Status is a report on the status of the QIBA Profiles and the progress made towards achieving the QIBA Profile Claims.

QIBA 2016 Status includes:

- Evolution of a QIBA Profile Claim
- QIBA Profile Claim Selection Flowchart
- QIBA Profile Claims

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