UPDATE ON QIBA COMPLIANCE

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QIBA “Industrializes” QI

- Select a Biomarker
- Coordinate Groundwork
- Draft Protocol
- Draft QIBA Profile

Apply selection criteria:
- Transformational, Translational, Feasible, Practical

Identify significant sources of variance

Estimate achievable repeatability and accuracy

Validate underlying assumptions and mechanisms

Determine details critical to specify in the Profile

Document the agreed parameters and procedures

Converge practice; reduce gratuitous variation

Initiate regulatory engagement

Specify details necessary to be robust in general use

Drive out any impeding variance and complexity

Make details stable, clear, implementable, testable

Test conformance with QIBA Profile specifications

Publish validated products/sites
### QIBA Profile Structure

<table>
<thead>
<tr>
<th>User Perspective</th>
<th>Claims:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will it do what I need?</td>
<td>&quot;95% probability that measured change -25% to +30% encompasses the true tumor volume change...&quot;</td>
</tr>
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<table>
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<tr>
<th>Vendor View</th>
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<tbody>
<tr>
<td>Why do you want me to do this?</td>
</tr>
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</table>

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<tr>
<th>Requirements:</th>
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<tr>
<td>What/who do I need involved?</td>
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**Actor Table**
- Scanner
- Measurement Software
- Radiologist

**Activity Definitions**
- Calibration / QA
- Patient Preparation
- Image Acquisition
- Reconstruction
- Post-Processing
- Analysis / Measurement
- Reading / Interpretation

<table>
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<th>Assessment Procedures:</th>
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<tr>
<td>What do I have to do (requirement checklists: procedures, training, performance targets) to achieve the Claims?</td>
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**RSNA 2014 QIBA Conformity Assessment System Design 4**

**Activity Requirements = Checklist**

- Table of "shall" for each activity
  - "The Technologist shall document subject height and weight."
  - "The Technologist shall set the Total Collimation Width to greater than or equal to 16mm."

- Some "shall" require a QIBA Assessment Procedure
  - "The scanner shall demonstrate In-plane Resolution of greater than or equal to 6 lp/cm and less than or equal to 8 lp/cm."
  - Assessment Procedure: In-plane Resolution
Assessment Procedures

Procedure Design
- Ideally, similar to existing procedures for QA/Certification
- Consult QIBA Metrology Group – methods, tradeoffs

Knowing the “Right” Answer
- Test Data Sets
- DRO (Digital Reference Objects) – think “synthetic phantom”

Not just for Conformance:
- Groundwork projects can use to confirm requirements and pick numbers
- Vendors can use before shipping product
- Sites can use to confirm performance

Assessment Scope
Assessment Patterns

<table>
<thead>
<tr>
<th></th>
<th>Self-Claim</th>
<th>Community</th>
<th>Formal Cert.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unit of Conformity</strong></td>
<td>Profile/Actor</td>
<td>Profile/Actor</td>
<td>Profile/Actor (Site?)</td>
</tr>
<tr>
<td><strong>Test Plan</strong></td>
<td>Standard Methods</td>
<td>Common Tools</td>
<td>Managed method &amp; tools</td>
</tr>
<tr>
<td><strong>Testing</strong></td>
<td>Vendor Testing</td>
<td>Test Events</td>
<td>Accredited Test Labs</td>
</tr>
<tr>
<td><strong>Certification</strong></td>
<td>Vendor Claim</td>
<td>Corroborated Claim</td>
<td>Accredited Certification Bodies</td>
</tr>
<tr>
<td><strong>Surveillance</strong></td>
<td>User reports non-conformity</td>
<td>Community Tracking</td>
<td>Formal Auditing</td>
</tr>
<tr>
<td><strong>Penalties</strong></td>
<td></td>
<td></td>
<td>Formal Penalties</td>
</tr>
<tr>
<td><strong>Remediation</strong></td>
<td>Next Release</td>
<td>Vendor Patch</td>
<td>Tracked Resolution</td>
</tr>
</tbody>
</table>

Also consider Periodic Assessment Vs Audit/Just-in-Time/Continuous Assessment

Scope Limbo: How low do we go?

Select Profile Candidate
Coordinate Groundwork
Perform Groundwork
Draft Profile Text
Publish Profile
Tech/Clinically Confirm Profile
Develop phantoms
Develop test plans
Develop test tools
Conduct Connectathons
Issue Product Certificates
Accredit Sites
Conduct Surveillance
Impose Penalties
...
Assertion of Conformance:

- Who will use the assertion
  - Img. Dept. Purchasers, Clinical Trialists, Clinicians, Payors, Regulators (State, Federal?), …

- What task(s) will the assertion affect
  - Purchasing, Site Enrollment, Data acceptance, Analysis, Diagnosis, Reimbursement, …

- What exactly should the assertion state to be useful

- What scope should the assertion have
  - product/component, total system/entire site
  - compliance to profile, overall performance

- Who should make the assertion
  - vendor, site

- What costs is the assertion expected to remove

- What costs (testing) are expected to achieve a given confidence

Extra Slides
Evolution of Claims

From QIBA Wiki:
"Claims: tell a user what can be accomplished by following the Profile"
  • Communicate Value to beneficiaries of the profile
  AND
  • State accurately and specifically enough to be testable

Metrology Working Group
• Vocabulary & Content (Repeatability & Reproducibility Coefficients, etc)

Next Steps
• Discuss/Incorporate Metrology into Profile Template (and profiles)

QIBA Profile Levels

- Progressive levels of stability and confidence

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<tr>
<th>Level Name</th>
<th>Level Meaning</th>
<th>Level Criteria</th>
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| Public Comment        | Profile describes key factors that affect the claim and procedures to address each/most of the factors. TC may modify. | • All Open issues clearly listed  
• Some groundwork may be ongoing  
• Actor requirements clear & justified  
• … |
| Publicly Reviewed     | Profile reasonably stable and ready for trial implementation. | • Public Comments addressed  
• Open issues mostly resolved  
• … |
| Technically Confirmed | Profile stable and ready for field use.            | • Profile results under experimental conditions consistent with Claim          |
| Clinically Confirmed  | Profile ready for broad use.                      | • Profile Claim achieved under clinical conditions                           |
DCE-MRI - Motivation

Possibility of interrogating tumor microvasculature and gathering quantitative information both for diagnostic, prognostic and therapeutic evaluation of cancer.
(e.g. Breast, prostate, rectal, cervix, HCC...)
DCE-MRI - Claim

Quantitative microvascular properties, specifically transfer constant ($K^{trans}$) and blood normalized initial area under the gadolinium concentration curve (IAUGC$_{BN}$), can be measured from DCE-MRI data obtained at 1.5T using low molecular weight extracellular gadolinium-based contrast agents with a 20% within-subject coefficient of variation for solid tumors at least 2 cm in diameter.

DCE-MRI

- Input variables
  - $T_1$
  - AIF
  - $S(t)$
- Problems
  - Signal fluctuation
  - $B_1$
  - motion
- Analysis
  - Model
  - Software
  - Quality
  - ROI
**DCE-MRI**

- Input variables
  - T1
  - AIF
  - Signal fluctuation
  - B1
  - motion

- Analysis
  - Model
  - Software
  - Quality
  - ROI

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**DCE-GE**

T1
DCE – Siemens Protocols

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DCE-MRI

Relevant Actors

– Vendor
  • Physicist
  • Software engineer
  • Service engineers

– Institution
  • Principal Investigator
  • Radiologist
  • Lead Technologist
  • Technologist
  • Image analyst

– Central Reading site

• Tasks
  – Scanner calibration
  – Phantom measurements
    • SNR
    • CNR
    • T1
    • Signal variation
  – Power injector
  – Image analysis
    • Hardware
    • Model
    • DRO
  – Human studies
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<td><strong>What do I have to implement; (requirement checklists: features, capabilities, performance targets)</strong></td>
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#### Claims:
- “95% probability that measured change -25% to +30% encompasses the true tumor volume change...”

#### Requirements:
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#### Assessment Procedures:
- Image Noise and Resolution
- Tumor Volume Change Variability
- Site Performance

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