QIBA PROCESS COMMITTEE
UPDATE

Kevin O’Donnell
Chair, QIBA Process Cmte
Sr. Mgr., R&D, Canon Medical Research USA, Inc.

Process Committee Scope

• Drive consistent content & format of Profiles
• Develop common Templates & Processes
• Support & mentor adoption of above
• Support infrastructure for Committees
Process Committee Structure

- **Chair:** Kevin O’Donnell
- **Vice-chair:** Dan Sullivan

**Coordinating Cmte Liaisons:**
- Cathy Elsinger (MR Coord Cmte)
- Brian Garra (US Coord Cmte)
- Edward F. Jackson (Steering Cmte)
- TBA (NM Coord Cmte)
- Nicholas Petrick (CT Coord Cmte)

**Biomarker Cmte Liaisons:**
- Michael Boss (DWI)
- Alexander Guimaraes (PDF)
- Feroze Mohamed (fMRI)
- Kevin O’Donnell (CTVol)
- Brian Zimmerman (FDG/PET)
- **Others welcome…**

**Scientific Liaisons:**
- Nancy Obuchowski (Metrology)

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Clinical Decisions from Quantitative Imaging

![Diagram showing clinical decisions process]
Everything should be made as simple as possible, but not simpler.

*Albert Einstein*

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**Pick your Battles**

- For each Source, consider:
  - **Cost/Difficulty to manage**
  - vs.
  - **Impact** on variability
Effort-Entropy Equilibrium

- TANSTAAFL (R. A. Heinlein)
- Conserve the link between requirements & claims
- Consider / Modify them in tandem

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Addressing sources of variability

After identifying factors that degrade performance...
- E.g. Head motion, small lesions, spiculated lesions

1. **Control (or compensate)**
   - Add requirement to use head immobilizer (or motion compensation)

2. **Separate claims for different subpopulations**
   - **Claim 1:** wCV=0.11 for 50mm lesions
   - **Claim 2:** wCV=0.25 for 10mm lesions

3. **Exclude subpopulation from claim**
   - **Claim holds for non-spiculated lesions**
95% Confidence Interval (CI)

- Interval where the true value lies with 95% confidence
  - Gives a practical sense of performance
  - E.g. measured SUVmax = 3.2, and the 95% CI = [ 2.9, 3.5 ]
  - Reflects both variability (interval width) and estimated bias (interval center)

- Example Usage: Estimated slope of line (β)
  - 95% CI for β = [-3.3, +5.0]
  - Interval contains 1.0, but is wide and contains many values not near 1.0
  - It would be wise to get more data!
“How to Write a Profile”

During the groundwork and drafting process, keep in mind the three primary functions of a profile:

- Tell vendors what can be accomplished by following the Profile. (Profile Claims)
- Tell vendors what they must implement in their product to state compliance with the Profile. (Profile Details)
- Tell users what they must do for the Profile Claims to be realized. (Profile Details)

Follow Profile Writing Guidelines

One of the hardest parts in drafting a Profile is figuring out what goes in, what to cut, and how to word things. Keep the following in mind when drafting the Profile. Look at these again when reviewing the Profile for publication at any stage.

- Put requirements in the Specification tables. The Discussion section is for additional information and can be skipped by folks who just want the requirements, saving additional requirements in Discussion would be sneaky.
- Start each table requirement with the word “shall.” It promotes direct wording and makes it clear this is a requirement.
- Searching a document for shall steps you through all the atomic requirements.
- Sentences that must, has to, needs to are not requirements so don’t confuse readers by using those words.
- Sentences with “should, could, might, etc.” are also not requirements but may be useful to provide informative recommendations.
- Don’t use “shall” outside of tables or procedures.
- Shall is for requirements. If it’s an activity requirement, put it in a table. If it’s not an activity requirement, don’t use shall.
- Use active voice.
- Physical Shall record the dateline of QC procedures “rather than “The dateline of QC procedures shall be recorded”.
- Passive voice makes it less clear who has responsibility for the requirement being met.
### QIBA Profile Stages

- Progressive levels of stability and confidence; **usage** depends on your needs

<table>
<thead>
<tr>
<th>Stage Name</th>
<th>Stage Meaning</th>
<th>Stage Criteria</th>
</tr>
</thead>
</table>
| Public Comment      | Key factors are described and addressed. Committee experts believe it practical and expect claimed performance will be achieved. | • Actor requirements clear & justified  
• Open issues clearly listed  
• Some groundwork may be ongoing |
| Consensus           | Wider review & consensus; ready for trial use.                                | • Public Comments addressed  
• Text reasonably stable  
• Open issues mostly resolved |
| Technically Confirmed | Profile is practical to understand and use.                                  | • Procedures implemented at test site  
• Text stable  
• Open issues resolved |
| Claim Confirmed     | Claimed performance can be achieved.                                          | • Performance measured at test site  
• Profile Claims achieved |
| Clinically Confirmed | Claimed performance will typically be achieved.                              | • Profile Claims achieved in clinical use at multiple sites  
• Note: QIBA doesn't currently evaluate or coordinate transition to this stage |

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**RSNA 2017**

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Public Comment -> Consensus

- Collate comments into a resolution spreadsheet
- Discuss comments; reach consensus
  - Consider a subgroup to handle “simple” ones
- Record resolutions
- Update Profile
- Review & Approve as Consensus
- Publish Consensus Profile & Resolutions Document

Comment Resolutions

![Screen shot of a webpage showing profiles and stages of development for technically confirmed profiles and consensus profiles. The image highlights comments resolutions and posts for public comments and post technical confirmations.]}
Comment Resolutions

<table>
<thead>
<tr>
<th>Document</th>
<th>Feedback Type</th>
<th>Feedback Closed</th>
<th>Resolutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT Profiles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>anthracoclasia 2019-02-29</td>
<td>Public Comment</td>
<td>2019-06-03</td>
<td>TBA</td>
</tr>
<tr>
<td>CT Tumor Volumetry for Advanced Disease 2015-11-21</td>
<td>Technical Confirmation</td>
<td>2017-02</td>
<td>Technical Confirmation Results and Resolutions</td>
</tr>
<tr>
<td>CT Small Lung Nodule Screening 2016-05-01</td>
<td>Public Comment</td>
<td>2016-09</td>
<td>TBA</td>
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<tr>
<td>MR Profiles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MRI Dwi 2015-02-05</td>
<td>Public Comment</td>
<td>2019-04-05</td>
<td>TBA</td>
</tr>
<tr>
<td>MRSI 2017-12-19</td>
<td>Public Comment</td>
<td>2017-12-31</td>
<td>TBA</td>
</tr>
<tr>
<td>MRU Endoscopy 2017-08-16</td>
<td>Public Comment</td>
<td>2017-08-15</td>
<td>TBA</td>
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<tr>
<td>MRI Dwi 2017-04-27</td>
<td>Public Comment</td>
<td>2017-08-25</td>
<td>TBA</td>
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<tr>
<td>PET/CT Profile</td>
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<td></td>
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<tr>
<td>PET Amyloid 2019-06-15</td>
<td>Public Comment</td>
<td>2017-06-15</td>
<td>TBA</td>
</tr>
</tbody>
</table>
Consensus -> Technically Confirmed

- Recruit/instruct/track Field Tests
- Collect results/feedback
- Evaluate/resolve feedback
- Revise Profile
- Review & Approve as Technically Confirmed
- Publish Tech. Conf. Profile & Resolutions Document

Technical Confirmation Process (Discussion)

- Confirm how it works in practice
  - Next step beyond reading the spec and commenting
  - What needs to be clarified?
    - Did multiple people follow the instructions the same way?
  - What needs to be changed?
    - Procedure too hard; bar too high?
  - Provides a dry run of conformance testing
    - Checklist format; Result capture
  - Develops a sense of useful details for testers to capture
    - What “shall”s and procedures were covered, passed
    - What/Who was tested – Device Models, Names
    - Where can we get more information – Contact info
Sunsetting Process

• Biomarker Committees
  – Dissolved
    • The work of the committee is completed
    • Result of an email ballot of the Coordinating Committee
    • Resources typically made available to the Steering Committee for reallocation
  – Dormant
    • The work of the committee is on hiatus for, say, 6-24 months
    • Result of an email ballot of the Biomarker Committee
    • Resources typically made temporarily available to the Coordinating Committee
    • Can be reactivated by an email ballot of the Coordinating Committee

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### QIAB Conformance Statement

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Product Name</th>
<th>Version</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>Any Medical Systems Co.</td>
<td>AlphaSmart</td>
<td>V2.3, V2.4, V3.3</td>
<td>2017-03-12</td>
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</tbody>
</table>

This product conforms to all specifications required for the QIAB Profiles and Actors listed below:

<table>
<thead>
<tr>
<th>Profiles Implemented</th>
<th>Actors Implemented</th>
<th>Notes</th>
</tr>
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<tbody>
<tr>
<td>CT Volume Change (2014)</td>
<td>Acquisition Device</td>
<td>See A.1</td>
</tr>
<tr>
<td></td>
<td>Reconstruction Software</td>
<td>See A.2</td>
</tr>
<tr>
<td>CT Volume Change (2017)</td>
<td>Acquisition Device</td>
<td>See A.3</td>
</tr>
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</table>

**Links to Additional Information**

- Shutter’s QIAB information: [www.anymedicalsystems.com/qiab](http://www.anymedicalsystems.com/qiab)
- General information on QIAB: qiab@iema.org

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**Annex A: Conformance Notes**

A.1 CT Volume Change (2014) – Acquisition Device

*Model-specific Instructions and Parameters*

The following parameter values were used when demonstrating conformance and are provided for reference. Other values may also achieve conformance.
QIBA Conformance Statement

<table>
<thead>
<tr>
<th>Site Name</th>
<th>Responsible Person</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mercy General Hospital - Oncology Dept</td>
<td>Dr. Marcus Sally</td>
<td>2021-03-12</td>
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</tbody>
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This site conforms to all specifications required for the QIBA Profiles and Actors listed below:

<table>
<thead>
<tr>
<th>Profiles Implemented</th>
<th>Actors Implemented</th>
<th>Notes</th>
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</thead>
<tbody>
<tr>
<td>CT Volume Change (2014)</td>
<td>Technologist</td>
<td>See A.1</td>
</tr>
<tr>
<td></td>
<td>Radiologist</td>
<td>See A.2</td>
</tr>
<tr>
<td></td>
<td>Site</td>
<td>See A.3</td>
</tr>
</tbody>
</table>

Links to Additional Information
- Sbmmaster's QIBA information: www.anatomicalsystems.com/qibs
- General information on QIBA: qibawiki.rsna.org

Annex A: Conformance Notes

A.1 CT Volume Change (2014) – Technologist

All technologists assigned to use this scanner received training that included details of this Profile. Periodic spot checks confirm they continue to follow the profile details.

A.2 CT Volume Change (2014) – Radiologist

All chest radiologists on staff have
- Reviewed the quality assurance guidelines described in section 3.4 of the profile
- Completed the performance assessment described in section 4.4 of the profile and met or