

### QIBA Profile Stages

- Over time we collect information, revise the Profile, and become increasingly confident of its ability to achieve the stated claim.
- Some users will find Profiles valuable even with only modest QIBA confidence, while others will count on achieving the claims exactly. In other words, some just want a spec to drive consistency and are happy with performance that is “whatever is as good as can be achieved with reasonably small effort” while others expect to achieve the claim performance numbers in practical use and will condemn QIBA if they do not.
- We don’t want to withhold Profiles until they are perfect and incontrovertibly accurate so as to avoid misleading anyone.
- Therefore, we should label Profiles to communicate the stage of maturity or confidence clearly and allow users to make their own choice about what they would like to use it for, *e.g.*, this is the Version for Public Comment of the QIBA Functional Brain Mapping Profile, or the Technically Confirmed Version of the QIBA DCE-MRI Profile.

Stage Name	Stage Meaning	Stage Criteria
<i>The tag we hang on the profile doc.</i>	<i>What we want users of this document to understand about what it means</i>	<i>The checklist items/metrics/Rules-Of-Thumb the document should have cleared before it can be released with this tag</i>
Stage 1: Version for Public Comment	<p>The Biomarker Committee (BC) finds that the Profile describes the key factors that affect the claim and has proposed recommended procedures that address each/most of the factors.</p> <p>The BC reserves the right to make modifications.</p>	<ul style="list-style-type: none"> <li>• All open issues have been clearly listed</li> <li>• Most open issues have candidate resolutions drafted into the Profile</li> <li>• Some groundwork projects may be underway</li> <li>• All major solution components and Profile details are complete enough to implement</li> <li>• For each actor in the Profile, it is clear what is required for a system or organization to claim conformance</li> <li>• Each activity in the Profile has a justification based on literature data, phantom studies, or TC consensus.</li> <li>• Conformance requirements appear sufficient to accomplish the Claim of the Profile</li> </ul>
Stage 2: Publicly Reviewed Version (Consensus Standard)	<p>The BC has formally addressed each issue raised during Public Comment. All Profile changes based on received public comments are documented.</p> <p>Implementers are encouraged to start implementing the Profile.</p> <p>The BC may modify requirements that fail feasibility testing.</p>	<ul style="list-style-type: none"> <li>• All public comments have been addressed</li> <li>• All open issues necessary for conformant deployment have been resolved</li> <li>• Few, if any, groundwork projects remain active</li> <li>• All recommended procedures have been tested in one or more groundwork project(s) or referenced studies. (Reasonable deviations from Profile details may exist.)</li> </ul>

<p>Stage 3: Technically Confirmed</p>	<p>The Profile details have been implemented in more than one facility and each individual actor (system and person) successfully met the specifications. The claim is yet to be confirmed in Stage 4.</p> <p>The BC asserts that deployments will find the Profile requirements practical/feasible to understand and execute. The BC may modify the claim or requirements if (stage 4) fails.</p>	<ul style="list-style-type: none"> <li>• All Profile procedures and details have been implemented on at least two vendor platforms and at two or more sites and found to be clear and not burdensome/impractical</li> <li>• An example of each Profile actor have demonstrated conformance</li> <li>• The BC will generally coordinate with sites/vendors to achieve this stage as it does with groundwork projects.</li> <li>• <i>Consider what documentation would be important. Think about how site conformance might be audited</i></li> </ul>
<p>Stage 4: Claim Confirmed</p>	<p>The Profile details have been implemented in more than one facility and each participating system and person successfully met the specifications; <b>the overall performance was determined and the claim was achieved.</b></p> <p>The BC asserts that conformant deployments can achieve the Profile Claim.</p>	<ul style="list-style-type: none"> <li>• Groundwork projects are complete</li> <li>• All Profile procedures and details have been implemented on at least two vendor platforms and at two or more sites</li> <li>• All Profile procedures and details have been tested in the field as described in the Profile</li> <li>• Profile results under experimental conditions are consistent with the Claim.</li> <li>• <i>Some claims (for patient-independent metrics) might be confirmable with phantoms/DROs (and may be part of assessment procedures) but likely measurement of performance in phantoms/DRO is not sufficient by itself to declare patient oriented claims to be confirmed.</i></li> <li>• <i>Q. how does all this play into conformance testing? QIBA Registry role? Mountain of data aggregation?</i></li> </ul>
<p>There are more stages that QIBA defines but are beyond the scope of QIBA to DO, e.g.:</p>		
<p>Stage 5: Clinically Confirmed Version</p>	<p>The BC has collected data broadly in the field on patients that confirm the claim.</p> <p><i>(The semantics of Clinically Confirmed and the criteria of</i></p>	<ul style="list-style-type: none"> <li>• All recommended procedures and Profile details have been implemented by multiple systems or sites</li> <li>• All recommended procedures and Profile details have been tested in the field as described in the</li> </ul>

	<p><i>this level are still under discussion)(QIBA won't DO this stage but may be a facilitator/enabler to get there)</i></p>	<p>Profile</p> <ul style="list-style-type: none"> <li>• The Profile Claim has been achieved in clinical conditions</li> <li>• <i>[Additional proposed criteria that will be discussed:</i> <ul style="list-style-type: none"> <li>○ <i>The degree of statistical certainty has been documented and exceeds ...</i></li> <li>○ <i>Some level of Clinical validation has been demonstrated</i></li> <li>○ <i>The Profile has been implemented in a human research study ]</i></li> </ul> </li> </ul>
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Versioning is a related question. For example, after the 2013 Edition of a Profile had been released for a few years, the technology and install-base might have advanced enough that we could release a 2015 Edition of the Profile that has a tighter claim and some additional constraints. We might write this as QIBA XXXX Profile (2015).