QIBA Process: Groundwork & Profiling

Concepts:

A Profile is an implementation guide. A Profile defines a problem and tells each participating system what it must be capable of doing, and how it must be capable of interacting with the other systems in the profile to solve the problem.

IHE has proven Profiles to be an effective method for getting sophisticated solutions implemented and tested in products. QIBA goes beyond IHE in the need for an additional layer. Research and validation, referred to here as Groundwork, is necessary to understand, quantify and prove some of the underlying assumptions and details.

Groundwork is intended to answer Precursor Questions so we can write Profile Details. The Precursor Questions should tie the Groundwork activities to the Profiling activities.

Proposed Groundwork activities should each answer one (or more) clearly stated Precursor Questions. If we can't identify a clear Precursor Question being answered, we should reconsider that Groundwork activity.

Precursor Questions should each be associated with a Profile Detail we need to specify or a Profile Claim we need to prove (also known as "requirements traceability").

Think of Profiles as making Profile Claims of what users will be able to do; and Profile Details are what we specify participating systems and people must be able to do if the Profile Claims are to be achieved.

Groundwork which does not answer Precursor Questions, or Precursor Questions that don't support Profile text can be moved down the "to do" list until we clarify what they're accomplishing.

Profiles, Precursors & Groundwork – A Strawman

The table is intended to help visualize the relationship between our activities, which in turn helps us plan/organize/prioritize/schedule those activities. We can identify cells we choose to address in "this cycle" and set some target deadlines. We can identify other cells as leading candidates for "next cycle". Some groundwork will be on the critical path to an early profile. Other groundwork will be critical to a profile we plan to do in the future, but is not critical yet. Some work will take a while so we may choose to get certain "future items" started now.

For the sake of argument, the table below is based on a sequence of three progressively ambitious Profiles. Each builds on the previous, each provides some useful capability, and each provides tools which will accelerate validation of the next.

Briefly:

1. QIBA **CT Volume Quantification** Profile claims to let users perform, store, exchange and analyze specific spatial measurements on acquired images.

2. QIBA **CT Tumor Volume Change** Profile claims to let users determine tumor volume changes to a certain level of accuracy across multiple acquisitions.

3. QIBA **CT Tumor Response** Profile claims to let users evaluate tumor "response" to a certain degree of confidence.

Strawman Alert: Constructive criticism is encouraged. All this is open to discussion. The table is far from complete and is largely off-the-top-of-the-head.

The contents of the Table are drawn (a bit haphazardly) from Validation Plan and QIBA Process documents.
In a loose sense, the Profiles are an incremental breakdown of the grand endpoint in the Strawman Matrix; the Precursor Questions should reflect the Strawman Matrix Challenges, and the Groundwork and the Profile Details should reflect the Mitigation Strategy/Action Items.
There seems to be little preventing us from doing the first Profile now. The second requires more groundwork done first, and the third is even further down the road. Deploying the first profile would make it easier to do the Groundwork for the second and third.

Profile Details	Precursor Questions	Groundwork
CT Volume Quantification Profile		
Claims:		
Can create, store, and retrieve the images on various systems	None. Proven capability with DICOM	
Can make useful spatial measurements on the acquired images.	What spatial measurements might be useful?	Evaluate measurements that show promise beyond RECIST (assuming that RECIST is one of the baseline measurements we decide to include) Consider extending the concepts of Modified RECIST (J. Natl. Cancer Inst. 2008;100:698-711) for wider cancer etiology than HCC. Note: if implementing a measurement tool is very easy,

		but conclusively proving it's clinical merit is hard, just err on the side of listing a few extra tools. This phase is about getting a good toolkit in place.
Can store, retrieve and process the measurements on various systems	None. Proven capability with DICOM SR	
Details:		
Specify the image acquisition activity (baseline protocol)	What acquisition parameters matter and what value ranges are acceptable?	Determine what constitutes a "baseline", and perhaps identify several higher levels, e.g. Level 2 parameters might be sufficient for 1cm+ nodules, but Level 3 parameters are required for <1cm nodules.
	Should we specify results (image resolution, noise level, etc), or method (kVp, mA, etc) or both?	
Specify the image exchange transaction	None. DICOM seems adequate for network and media interchange.	
Specify the measurement activity	Should we specify results (e.g. require compliant systems to simply provide an estimate of the volume) or method (e.g. require compliant systems to implement a specific method, such as a model-based one including major axis and two minor axis lengths for an assumed bounding ellipsoid)	
	Should we permit/require "true volume" measurements and model-based approaches?	
Specify the measurement exchange transaction (Use DICOM)	What additions are needed to DICOM SR Templates to support the measurements specified in the measurements activity (above)?	

CT Tumor Volume Change Profile		
Claims:		
Can measure Tumor Volume Change to a certain degree of accuracy across multiple studies	What is our targeted degree of accuracy for volume change? (i.e. what accuracy is clinically meaningful?)	Analyze NCI RIDER lung tumor images. (See Part I, Stage B1 & B2 in Mozely Validation Roadmap)
		Establish metrics
		Determine metric value that is required for acceptance (See Part II, Stage A1 & A2 in Mozely Validation Roadmap)
	Can we demonstrate that degree of accuracy is achievable?	
Can acquire the studies on different systems/models		(See Part I, Stage A3 in Mozley Validation Roadmap)
Can perform the measurements using different measurement packages		(See Part I, Stage A2 in Mozley Validation Roadmap)
Can perform the measurements with different operators	How big an impact is inter-observer variation?	(See Part I, Stage A1 & A2 in Mozley Validation Roadmap)
	How should we manage the variation?	
Details:		
Specify patient preparation activity to control sources of variability, or else record sources of variability to allow for compensation	What details significantly affect inter-study variability of tumor volume measurement?	Identify details likely to vary between studies and estimate impact.
Specify acquisition activity to control sources of variability, or else to record sources of variability to allow for compensation	What acquisition details significantly affect inter-system variability of tumor volume measurement?	Identify details likely to vary between systems/models and estimate impact.
		(See Part I, Stage A3 in Mozley Validation Roadmap)
		Establish clinical retrospectively acquired data base having well defined patient outcomes (overall survival, time to progression, and possibly quality of life), multiple scans and recorded scan details. (Start mapping such resources in the Wiki Catalog page.)

	What "minimum values" need to be achieved for identified key acq. details?	(Refer to Part II, Stage B of Mozley Validation Roadmap)
Specify measurement activity performance targets or else specify detailed methods to manage sources of variability.	What measurement details significantly affect inter-system variability of tumor volume measurement?	(See Part I, Stage A1 in Mozley Validation Roadmap)
	What baseline accuracy targets should we specify?	
	Do the user interactions have a sufficiently large impact on accuracy that we should specify them?	Establish image database using FDA Anthropomorphic Phantom (believed to be the more challenging phantom when the "inserts" are included)
		Perform trial with controlled operator but different packages
Specify measurement activity details	Is it necessary to incorporate terms for change (e.g. ordinal scale 1-5 for degree of change)?	
Specify the measurement training activity	What is the inter/intra-observer variation?	Quantify intra/inter-observer variation. (See Part I, Stage A1 and Part I, Stage A2 in Mozley Validation Roadmap)
	Is the inter/intra-observer variation large enough, relative to the accuracy targets (above), that it needs to be controlled?	
	Can user training effectively control inter/intra-observer variation?	
Specify the site benchmarking/ validation activity	What tests should a site perform to prove it can meet the required performance levels?	(See Part II, Stage C of Mozley Validation Roadmap)

CT Tumor Response Profile		
Claims:		
Can evaluate tumor response to a certain degree of confidence.	What do we mean by "tumor response"?	(See Part II, Stage A2 of Mozley Validation Roadmap)
	Do we have enough accuracy to measure basic response categories?	(See Part III, Stage A of Mozley Validation Roadmap: Quantification of sensitivity and specificity in distinguishing categorical response variables, including Partial Response (PR), Stable Disease (SD), and Progressive Disease (PD))
	How does this profile compare to RECIST? Is it better?	(See Part III, Stage B of Mozley Validation Roadmap: Correlate 3D image analysis and "latent gold standard", i.e. RECIST)
	Is volume change a valid surrogate end-point for tumor response?	<Refer to David Mozley clinical protocol update>
Details:		
Specify what volume change accuracy is adequate for tumor response evaluation	What accuracy is adequate?	(See Part III, Stage A of Mozley Validation Roadmap)

Work can happen in parallel. A number of Groundwork activities will be going on at the same time. Profile writing can start now and doing so will uncover additional Precursor Questions. Profile sections can be sketched in and revised as the Precursor Questions are answered. We may find that some sketched sections are sufficient as they are and that Precursor Question can be deferred til later. We may realize that some Profile Details are not necessary to achieve the Profile Claims. We may realize that additional Profile Details are necessary to achieve the Profile Claims.

Even if we are not publicly releasing the Profiles early on, this approach should keep activities closely tied to practical implementations.

The Profile Details have started to introduce the idea of specifying activities (things a system must be capable of doing itself, e.g. making certain measurements or performing a certain calibration) and specifying transactions (things one system must capable of conveying to another system).