QIBA Profile Development Update (Dr Mozley)

- Dr Mozley provided an overview of the latest revision made to the QIBA v-CT Chest V1.4 protocol adapted from Mr O'Donnell's previous version found on Google docs.
  https://docs.google.com/Doc?docid=0ASSwlnzdbbPEGZJyc2pxcF8zcHFkdnhqY3A&hl=en
- Word version needed for distribution with current date (09.13.2010) for identification.
- Action required to create next version (V1.5) in time for the QIBA Working Meeting at the RSNA 2010 Annual Meeting.
- Protocol formatted based on the UPICT Template.
- Mr O'Donnell described concern over placeholder values and proposed protocol authorship be handed-over to a content expert such as Dr McNitt-Gray to help build robustness.
- Multiple protocol versions needed based on specific use, with a public comment stage similar to the IHE process; draft/version numbering is critical, e.g. V1.0, 1.1, 1.2, 1.3…
- Need to reach consensus and determine "good-enough-to-go" under the QIBA name release point; protocol must spell-out all limitations.
- Definitions from DIA added to appendix by Dr Mozley (source needs to be cited).
- Caution concerning use of “draft” version; draft not truly implementable until reviewed by industry and academia for official consensus; QIBA authorizes “trial implementation” as part of its review process; QIBA review and approval process is being determined but the IHE concept of trial implementation is reasonable here as a way to gain experience both for this specific protocol as well as for development of the review methodology in QIBA.
- To move beyond “trial implementation”, line-by-line review needed (as with Profile review); face-to-face meeting considered best scenario, followed by t-cons, depending on level of material for review.
- Goal setting language needed; what do we want to achieve and what has been achieved.
- Having evidence to support values in the protocol is desirable. List references-to-date in support and determine what isn’t supported by current data.
- Audience – potential for release.
  o Pharma seen as major audience; launching numerous drug trials now.
  o QIBA v-CT Chest V1.4 considered the best protocol available.
- Sections X and XI.
  o Could be replaced with boilerplate text in UPICT template.
  o Rules for lesion boundary definition important.
  o Standard performance for data management needs to be addressed.
  o Replace values with XX, unless values confirmed.
- Adherence to parameters needs to be emphasized.
Response Criteria

- Response criteria for volumetric based measurements deemed beyond current scope of QIBA; different content experience needed to deal with this topic; no response criteria in V1.4 noted
- Group consensus was to keep master protocol copy in **Google docs** for ease of editing; download to MS-WORD or PDF possible with line numbers

Next Steps:

- Writing assignments to be implemented; domain experts needed to define specific contexts
- Dr Mozley to email group once his current edits were re-introduced/combined with the Google doc
- Next call scheduled for: Monday, Sept 27, 2010 at 11 am CDT