QIBA Q-CT Committee Weekly Update
Monday, June 7, 2010
11 AM CDT

Draft Call Summary

In Attendance
Kevin O'Donnell (moderator)
Maria Athelogou, PhD
Charles Fenimore, PhD
Kavita Garg, MD
James Mulshine, MD
Anthony Reeves, PhD
Yuanxin Rong, MD, MPH
Daniel Sullivan, MD
David Vining, MD
Binsheng Zhao, DSc

RSNA
Fiona Miller
Joe Koudelik

Overview of the 2010 QIBA f2f meeting and Q-CT breakout session (Kevin O'Donnell)

- Focus of discussions were to reconfirm the "Value Story" of why QIBA pursuing qualification, e.g. CT is a widely deployed tool, pathway for biomarker qualification needed, qualification would benefit numerous stakeholders, etc
- Content for use discussed; must prove CT quantitation is accurate and reproducible and prove useful as a surrogate for other measures
- "Master file" of raw data needed to prove assumptions; targeted qualification next level
- Volume to be the first step, with lesion change-of-shape pursed in future, e.g. shape change, time texture perfusion – all useful biomarkers beyond volume

The Qualification Journey

- First pass work useful; work with CDER to structure Profile Claims and needed tests
- FDA feedback expected with this iterative process

Briefing Document: Literature Review

- Good start with many topics and supportive material; identification of additional material welcome
- Need to review articles critically to identify possible gaps, statistical weaknesses, or outdated methods, i.e. potential red flags
- Interpretation section to be added to lit criteria

Briefing Document: Purpose of Profiles

- Selection of protocol values based on public comment phases, footnotes on "target" values with evidence references or rationale
- List attributes that affect biomarker Claims
- Attributes need a set acceptable level; identify what makes data unfit
- Target and Ideal performance levels to be optional; only specify if this performance level truly helps results; justification needed

Briefing Document: Experimental Groundwork

- Non-inferiority comparison trials; need to prove biomarker (volume measure) better or comparable to RECIST based on experimental groundwork

European Q-CT Committee members asked for additional factors to consider

- Quality assurance (QA) personnel to be included in discussions/feedback to prepare for FDA talks
- Process will basically be U.S. driven, but welcome European and Asian counterpart input, i.e. activities needed to validate biomarkers abroad

Next Steps:

- Continue literature reviews; circulate among all Q-CT members for feedback; send reference plus 1-2 paragraph summary of literature review
- Forward favorite literature reviews for bibliography file
- Dr Garg to draft list of key points to base literature reviews requirements on and forward to the group
- U Colorado Cancer Center welcome to assist with Siemens 64 scanning
- Dr McNitt-Gray and Mr O'Donnell to evaluate Q-CT Group 1A data offline; compliance classification done; schedule t-con for next week