

QIBA VoICT Update WebEx
Monday, June 1, 2009
11 AM (CDT)

Call Summary

In attendance:

Andrew Buckler, MS (Co-Chair)
P. David Mozley, MD (Co-Chair)
Kristin Borradaile
David A. Clunie, MBBS
David Gustafson, PhD
Michael McNitt-Gray, PhD
James Mulshine, MD
Nicholas Petrick, PhD

Anthony P. Reeves
Daniel Sullivan, MD

RSNA
Susan Anderson
Joe Koudelik

Review of Agenda

Review of posted Profile, now in UPICT template format and discussion on readiness of template:

1. Is it useable by pharma?
2. Is it actionable by vendors?

Discussion of posted Profile in UPICT template

- Drs Mulshine and Mozley will consider the utility of developing a questionnaire or evaluation tool for protocol user feedback
 - Can expect feedback when protocol is distributed by pharma to trialists; using spiral model, changes can be made concurrent with use
- Ongoing issue of alignment with UPICT template:
 - Work to align 1-1 with UPICT template or add/delete sections unique to QIBA
- Claims language will be re-inserted between Sections 2 and 3
- Discussion of change-control process for document
 - Informality of Wiki editing appropriate for current/early stage of Protocol versions
 - In 3-6 months will be useful to name an editor who will make and monitor subsequent changes
- Discussion of alternate arrangement of document grouping all Ideal, Target and Acceptable specifications together
 - Need to describe interactions in fine detail if possible
- Decision to annotate for discussion and make refinements on Wiki but to refrain from extensive deletions before group discussion
- Original language addressed vendors as audience; Profile has been influenced by pharma needs; important to consider both
- Discussion on Sections
 - Section 2
 - Language was extracted from 'clinical context'; is it sufficient/scalable to address 2 protocols – late stage and early stage lung cancer?
 - Sections 6.7-6.8 and 6.11-6.13
 - Want a Protocol which provides executable directions, not theoreticals
 - QIBA has an educational mission and should provide context
 - QIBA aim is to produce a 'recipe book' but with consideration that utility is determined by more than supplying tools; the ultimate need is for translation, i.e. translation of Protocol parameters into actual scanner setting required for all vendors
 - Vendors to provide details

- Reconsider discussion related to inclusion of Isotropic Voxels (which require much thinner slices and are only meaningful in **Ideal** slice thickness) and Field of View
- Section 9
 - Suggestion to remove or soften the specifics of Section 9 on policy/trial logistics (e.g. transfer and archiving of images); language was taken from UPICT template
- Section 14
 - Quality control currently is Appendix; discussion of placement in Appendix versus in body of template

Next steps:

- Dr McNitt-Gray will remove Section 6.11-13 and will also provide context language for Section 2
 - Additional details needed, goal of trial, etc
- Insert Claims between Sections 2 and 3
- New template can serve as basis for Profile of small nodule in neo-adjuvant setting
- Insert statement of purpose (what we are or are not trying to accomplish) and also statement describing dosage, i.e. low dose or high dose protocol