

QIBA Volumetric CT Technical Committee Update Call

October 3, 2011 at 11 AM CDT

Call Summary

In attendance:

P. David Mozley, MD (Co-chair)
Hubert Beaumont, PhD
Andrew Buckler, MS
Patricia Cole, PhD, MD
Alden Dima, MS
Charles Fenimore, PhD
David Gustafson, PhD
Philip Judy, PhD
Michael McNitt-Gray, PhD
David Miller, PhD
James Mulshine, MD
Kevin O'Donnell

Nicholas Petrick, PhD
Anthony Reeves, PhD
Ehsan Samei, PhD
Ann Scherzinger, PhD
Daniel Sullivan, MD
Ying Tang, PhD
Binsheng Zhao, DSc

RSNA:

Joe Koudelik
Madeleine McCoy

Topics for discussion

1. VolCT Tech Ctte poster update for RSNA 2011 kiosk area
2. Clinical trials guidance for the FDA responses – understanding section relationships

VolCT Tech Ctte poster update for RSNA 2011 kiosk area

- Dr Mozley and Mr Buckler provided an overview of the proposed 2011 VolCT TC poster layout, section by section
- Introduction is to retain purpose and aims of what the Tech Ctte is attempting to accomplish
- Need to highlight new results
- Title change proposed; “Quantifying Change in Tumor Volumes as Response to Treatment”
- “Volumetry” a new catch-term to be used
- Goal of poster is to draw in people and provide project updates without overwhelming them with detail
- Deadline for submitting material to Dr Mozley will be close-of-business on October 14, 2011, to meet the RSNA deadline of November 4th, 2011
 - Close-of-business meaning Sunday evening (Oct 16, 2011)
 - RSNA staff to distribute material received the on Oct 17th, before the 11 am (CDT) VolCT call
- [2010 QIBA Kiosk posters](#) are available on the Wiki for reference
- QIBA Kiosk area will have high-level mission, process, organizational and committee details

Project leader updates for kiosk poster

- Introduction – Mr Buckler and Dr Mozley to provide current activity and overview of 2010 progress
- 1A - Dr Petrick to provide latest results for the 1A study; only study that speaks towards accuracy
- 1B - Dr McNitt-Gray to provide preliminary details; methods, images, result graphics and next steps
- 1C - Dr Fenimore to provide update
- 3A - Dr Athellogou to provide statement of 3A challenge goals
- 3B - Dr Zhao to provide summary of project goals and those obtained so far
- Duke project – Dr Chen and Samei to provide update
- U Colorado project – Dr Garg/Scherzinger/Miller to provide update

- Profile development – Mr O’Donnell to provide overview of what the VolCT Tech Ctte has done with Profile development (i.e., acquisition protocol, segmentation analysis, QA, certification methods, etc) “What is a Profile” detail not needed; this will be provided on the QIBA kiosk for general reference

<p>Introduction; Buckler/Mozley</p>	<p>1B Summary Reflect on the original and the current change in the workflow: McNitt-Gray</p>	<p>1C Summary Restatement of 2010 poster text plus expected preliminary results for 2011: <u>Fenimore</u></p>	<p>Duke Project Summary: Chen to discuss with <u>Samei</u></p>	<p>3A Statement of Challenge Goals; Athelougou</p>
<p>1A Results; <u>Petrick</u></p>			<p>Colorado Project Summary: <u>Garg/Scherzinger/Miller</u></p>	<p>3B Summary; Zhao</p>

Note: Proposed size restriction for each segment/column is: 15.2” x 47”

FDA Clinical Trials Guidance – Mapping within Sections

- QIBA’s one and only chance to react to the FDA’s imaging guidance request
- Influencing the FDA guidance vs. addressing gaps within QIBA Profiles/Protocols discussed; caution not to be overly detailed in response since this guidance goes beyond QIBA’s scope
- The Tech Ctte concluded to compile a conservative response with hopes that the FDA will eventually reference QIBA when discussing quantitative imaging
- Tech Ctte feedback solicited in similar format as used for Profile Public Comment; three responses submitted to Mr Buckler; comments to Mr Buckler still welcome past the Oct 3rd deadline
- Mr Buckle to draft a compiled response for review by QIBA leadership
- Response matrix (tool) to assist with QIBA responses discussed
 - FDA Guidance Text
 - Mapping to UPICT Protocol Template
 - Mapping to QIBA Profile Template
 - Feedback to FDA
- Pharmaceutical Imaging Group (PIG) response timeline reviewed
 - Draft comments done (10/0/2011)
 - Legal review (10/12/2011)
 - Finalized pharma response (10/17/2011)
 - Forward responses to FDA (10/18/2011)
- Mapping within document sections discussed

Next steps:

- Final poster content to be discussed on the next call, Monday, Oct 17, 2011, prior to handoff to the Merck graphics team
 - Deadline for submitting material to Dr Mozley will be by Sunday evening , Oct 16th
 - RSNA staff to distribute material received the morning before the 11 am (CDT) VolCT call on Oct 17th
- RSNA staff to follow-up with Drs Athelougou and Garg concerning poster details and deadlines
- FDA imaging guidance feedback needed by Mr Buckler by mid-week (Oct 5)
- Reminder: Next VolCT TC call scheduled for Monday, October 17, 2011 (no call scheduled for Oct 10th)