

**CTSA UPICT Subgroup meeting**  
**Wednesday, November 4, 2009**  
**12:30 – 4:30pm**  
**In conjunction with Imaging Biomarkers Roundtable**  
**RSNA, Oak Brook, IL**

**In attendance:**

Gary S. Dorfman, MD (moderator)	Daniel C. Sullivan, MD
Ronald R. Boellaard, PhD	Walter Wolf, PhD
Patricia E. Cole, MD, PhD	Jeffrey Yap, PhD (via WebEx)
James Frost, MD, PhD, MBA (via WebEx)	<b>RSNA</b>
Otto Hoekstra, MD, PhD	Linda Bresolin
P. David Mozley, MD	Fiona Miller
Kevin O'Donnell	Susan Anderson
Eric S. Perlman, MD	Mary Cerceo
Rohit Sood, MD	

**General discussion**

- UPICT goal is to develop uniform protocols for clinical trials, encourage the use of imaging as an endpoint in trials and raise the quality of imaging in clinical practice
- Have completed a protocol template and are extracting proffered protocols into that template
- Eventually will create de novo protocol or will harmonize proffered protocols as a consensus protocol

**Submission Cover sheet and Minimum Threshold criteria (Dr. Dorfman)**

- Type of trial in which imaging protocol was used is an important criteria
  - Decision to ask volunteer extractors to complete and test Submission Cover Sheet
- Issues related to calendar and timing of imaging within clinical trials will be addressed in the instructional template; perhaps subcommittee could anonymize trial calendar of drug names but provide class of drug
- Include 'disutilities' or limitations in Section 1.1
- Drs Perlman and Dorfman and Mr O'Donnell to continue discussion of Netherlands extraction
- Dr Mozley will edit executive summary section of QIBA lung protocol to remove wording such as "twice as sensitive as RECIST"
- Submission Cover sheet will be shortened and re-ordered by Dr Dorfman to include a Go-No Go question near the top of the form

**Minimum threshold criteria**

- Do not reject if submitter has not received funding; some trials are self-funded
- Change FDA to 'appropriate regulatory agency' throughout document
- Change 'published' to 'scientifically rigorous process'
- Include current IRB approval, e.g. must have been used in a clinical trial approved by an IRB, add text 'approved by IRB' or a reasonable minimum criteria
- Include criteria of 'listed in a clinical trials directory such as [clinicaltrials.gov](http://clinicaltrials.gov)'
- Add 'national' to the list of independent review agencies
- Dr Dorfman to incorporate changes and send to RSNA staff for distribution to committee

## Template and Extractions

- Submitters will be requested to extract protocol into UPICT template
- Template is extremely comprehensive; somewhat challenging to complete because of detail
- Address Section 1 which is extremely trial specific in instructional template
- Discussion of funding for services such as review and extraction
  - Consider exploring competitive bid (RFP) process for extraction
  - Consider payment for reviewers and UPICT Deputy Editor
- Volunteers to review extraction and check blank areas; UPICT will not re-author but may add a notes or editorial comment, literature citation or direction to instructional template
- Mr O'Donnell discussed presentation of data in sections 7.1-.3 and Appendix G tables which address those sections as well as acquisition and recon

## Workflow

- Solicitation of protocols has been informal to date; as workflow is streamlined, will consider formal solicitations to groups such as bio, pharma and CROs
- Proffered protocols will be submitted with Submission Cover Sheet and suggestions from submitter for meta-tags
- Submitted protocols will be vetted by staff and volunteers following clear, simple threshold criteria
- Consider mimicking journal process by assigning a team leader who then assigns reviewers.
  - Send email to committee members to ask if they would like to be a reviewer; let reviewers know time commitment and work load.
- Place executive summary at the top; include bylines.
- The main editorial team reviews the submitted protocol and posts on the Wiki for comment
- CTSA IWG email blast to let the committee know a protocol has been posted
  - Docs will be posted on the Wiki in pdf format, the community will comment but not change
  - Determine conventions for comments, e.g. yellow highlighting, angle brackets to show questions, square parentheses to insert words.
  - Consider 30 day comment period
  - Google docs could be used as a tool for review at team leader's discretion
  - Dr Yap noted VIEW 'virtual imaging extraction workspace' as a model to be considered
- Comments assembled and adjudication process scheduled
- Submitter of template will receive comments; submitter and team reach adjudication by WebEx; anyone who submitted a comment is invited to the WebEx.
- Post protocol to searchable library
  - Library should include capability to search on sections of protocol such as trials calendar, acquisition protocol pr patient preparation
  - Determine periodic review and maintenance process of Library protocols

## Teams

- Team for ACRIN FDG-PET and SOPs: Drs Yap (leader), Siegel, van den Abbeele
- Team for ADNI MR portion: Drs Schwarz (leader) and Cole and Mr Hill (ixico)
- Team for ADNI PET section: Drs Frost (leader)and Cole
- Team for Netherlands protocol PET: Drs Perlman (leader), Boellaard and Hoekstra
- Team for QIBA PET Profile when completed: Drs Kinahan (leader), Cole, Perlman and Mr Buckler

- Team for QIBA vCT Profile: Mr O'Donnell (leader), Mr Buckler and Drs Mozley and Schwartz
- Team for Instructional-Educational UPICT document: Drs Patt (leader) and Dorfman and Mr. O'Donnell

### **Consensus protocols**

- Pathways include
  - 1.) data and evidence of 'one' best protocol or
  - 2.) uniformity through consolidation, expert opinion, etc.
    - Decision that QIBA pursues pathway 1; UPICT process will fall in between 1 and 2
- Possibilities for consensus process include basing consensus on clinical literature or protocol most use in marketplace; discussion to continue

### **Next Steps:**

- Need for volunteers to extract protocols and to assemble teams who will guide extraction through draft proffered process into review period
- Dr Dorfman will review Submission cover sheet and workplan to include suggested changes
  - Submission Cover sheet will be re-ordered by Dr Dorfman to shorten and include a Go-No Go question near the top of the form
- Dr Dorfman to incorporate changes to Minimum Threshold Criteria and send to RSNA for distribution to committee
  - RSNA staff will post on wiki when complete
- RSNA staff to upload Jeffrey Yap, PhD extracted SOPs and email Kevin O'Donnell when this is complete.
- Issues related to calendar and timing of imaging within clinical trials will be addressed in the instructional template
- Dr Frost will continue work on ADNI protocol with Dr Cole
- Dr Mozley will edit executive summary section of QIBA lung protocol to remove wording such as "twice as sensitive as RECIST"
- Increase submitted protocols by using word of mouth within CTSA membership
- Clinical Trials/UPICT group to meet at RSNA, Tuesday, Dec 1, 4:15-6:00pm
- Discussion to include a review of proffered protocols and continued discussion on consensus protocols