

**CTSA Clinical Trials/UPICT March Update WebEx**  
**Tuesday, March 3, 2009, 3:00PM (CST)**  
**Draft Call Summary**

**In attendance:**

Gary Dorfman, MD (moderator)  
Thomas FitzGerald, MD  
P. David Mozley, MD  
Luna Hilaire, PhD  
Walter Wolf, PhD  
Adam J. Schwarz, PhD  
Eric S. Perlman, MD  
Orhan Suleiman  
Daniel Sullivan, MD

Bradford Navia  
Patricia Cole, MD, PhD  
Wen-Lin Luo  
Vahe Ghahraman  
Gordon Harris, PhD  
**RSNA**  
Linda Bresolin, PhD, MBA, CAE  
Fiona Miller  
Susan Anderson  
Mary Cerceo

**Protocol Template Domains (Dr. Dorfman)**

- Modality-dependent domain: specific for each modality:CT, MRI, FDG-PET/CT, re: site and equipment, tech parameters, acquisition parameters, data management and post processing, quality control/assurance
- Modality-independent domains:
  - Universal or “agnostic”; domains dependent on the purpose of trial, disease, use and protocol.
  - Modality-independent domains:
    - Proposed utility(ies) of the imaging tests within the clinical trial
    - Pre-enrollment imaging tests.
    - Timing of imaging tests within the clinical trial calendar
    - Off-protocol imaging
- Dr. Mozley emphasized importance of including specific values when known

**Review of draft documents (Dr Dorfman)**

**1. Draft submission cover sheet to be completed by institutions submitting protocols**

- Automate with check boxes or a pull down menu (electronically submittable)
- Attempt to standardize the language
- Distinction to be made between accruing and imaging site

**2. Draft criteria of “Minimum Threshold for Acceptance for Posting as a UPICT protocol”**

- Will include only imaging portion of a protocol
- Addresses both multi-site and single-site trials
- Criteria will be posted so it can be determined if a study meets the minimum criteria.
- Item #4 “...received review through an independent review process or federal agency”, suggest adding academic institution or cooperative groups and equivalent European agencies

### 3. Annotation Domains and Metrics for Posted Protocols

- Product will be a searchable index with annotations/keywords/indexing terms.
- Annotations will facilitate comparison of protocols: same protocol/different purposes or same modality/different disease
- Search criteria will be listed on drop down menus
- Suggestions for changes:
  - Add kinetics, pharmacokinetics, pharmacodynamics
  - The subsequent iteration will have modality domains populated.
  - Under 1. Modality, add contrast domain
  - Under 2.a. Disease state/cancer, list cancer types and stage
  - Specify pull-down for anatomic sites, using standard nomenclature
  - Under 3.h. provide examples e.g. response assessment, validated or qualified for disease-specific
  - Consider alignment with QIBA Technical committees' image acquisition parameters: behavioral/technical

### Priorities for Work Product at IRAT/CTSA Joint Workshop in Baltimore

- Nominations for protocols needed from committee:
  - **VolCT:** ACRIN 6678, lung cancer, may be problematic, uses "off-label" protocol
    - Vol/CT: Volumetric CT is important; QIBA is also working on Volumetric CT including lung protocol (ACRIN 6678); info at the QIBA Wiki
    - Create a template that works for QIBA Volumetric CT tech committee and for pharma
    - Work towards links between UPICT and QIBA .
  - **FDG-PET:** [The Netherlands protocol for standardisation and quantification of FDG whole body PET studies in multi-centre trials.](#) Boellaard R, Oyen WJ, Hoekstra CJ, Hoekstra OS, Visser EP, Willemsen AT, Arends B, Verzijlbergen FJ, Zijlstra J, Paans AM, Comans EF, Pruim J. Eur J Nucl Med Mol Imaging. 2008 Dec;35(12):2320-33. Epub 2008 Aug 15.
  - **MRI:** ADNI protocol for brain or ACRIN knee protocol--need nominations from group for MRI protocol
- Examples will be abstracted in Baltimore; at the conclusion of the Baltimore meeting, the committee will have a product to send and post.

### Next Steps:

- The committee is urged to refine, edit and submit suggestions and additions to draft documents.
- Committee members are urged to comment and provide input on the functionality of the library "What would you like to search on?"
- A CTSA Wiki workspace is available for group use
- The group will submit additional nominations for the template
- Steve Drew (RSNA) will call in for last 90 minutes of Baltimore UPICT Monday breakout session meeting to discuss informatics and database issues
- Next WebEx: Thursday April 2, 11:00AMCDT