

**IRAT Network/CTSA Imaging Working Group Joint Workshop  
Baltimore, MD  
March 29-31, 2009**

**Summary**

**Joint Workshop sessions**

The Joint Workshop was convened with both joint and separate IRAT and CTSA programming sessions. The joint sessions focused on *Imaging Response Assessment* (including presentations on data-sharing, RECIST 1.1 and the SCARD survey), *Building Relationships and Fostering Collaboration* (including presentations on the perspectives of a cancer center, a clinical researcher and a CTSA core on training, organization, trial design and validation of imaging biomarkers, funding and reimbursement), *Cancer Center Processes in Protocol Review* (including presentations on integrating imaging early in the protocol design process and privacy and proprietary issues) and *Imaging Research Cores: Functions, Management and Cost* (with reports from institutions and a presentation on the use of para-professionals in core functions). The panel/group discussion format facilitated questions and information exchange.

**CTSA Imaging Working Group (CTSA IWG)**

The last 1/2 day of the meeting was devoted to CTSA IWG programming and report-back on activities and next steps from two CTSA IWG subgroups--Imaging in Clinical Trials (UPICT) and Cores/Education—which met face-to-face in two sessions during the workshop.

Dr. Daniel Sullivan invited attendees' input on defining the needs of the CTSA's and the best approaches for efforts, particularly in the areas of collaboration and imaging informatics. In a presentation on the *National Center for Research Resources (NCRR) Vision for the CTSA Consortium*, Dr Douglas Sheeley highlighted NCRR organizational structure and funding mechanisms and directed attendees to information on the [CTSA website](#) which details the [administrative supplements](#) from NCRR funds which are available to investigators and U.S. institutions or organizations with active NIH research grants.

**CTSA IWG subgroup report: Imaging in Clinical Trials (UPICT)**

- Imaging in Clinical Trials (UPICT) PowerPoint presentation by Dr. Gary S. Dorfman

The CTSA Imaging Working Group Imaging in Clinical Trials (UPICT) subgroup has among its goals:

- To reduce variance related to imaging in the conduct of early and late-phase clinical trials to support both translation and clinical indications;

- to allow the detection of differences that are a consequence of the intervention under study, not an artifact of the manner in which the imaging is conducted; and
- to support optimization and validation of imaging biomarkers (e.g. platforms, agents, algorithms).
- To improve the likelihood that clinical imaging studies will comply with clinical trial protocol expectations and that clinical trial imaging protocols will “fit” with practice
- To provide a subtle impetus to improve standard of care, thereby increasing the chances that pre-enrollment imaging might be used as “baseline” study

To meet these goals, the short-term UPICT objectives underway include:

- Design and review of a standard imaging protocol template(s); and
- Development of:
  - a web-based workspace and supporting infrastructure to facilitate the submission, vetting, and annotation of Proffered Protocols in a transparent and inclusive expert review and approval process
  - a web-based resource library of annotated Proffered Protocols that have been used to support clinical trials within institutions, cooperative groups, and trials consortia that meet a minimum set of criteria
  - a web-based workspace and infrastructure to facilitate the iterative authoring and periodic review of Consensus Protocols in a transparent and inclusive manner; and
  - a web-based environment to facilitate the interaction among clinical trialists and imaging scientists within academia, industry, and agencies

Work during the breakout sessions focused on completing revisions to the draft standard imaging protocol template and extracting proffered protocols (including a Netherlands FDG-PET protocol, ACRIN 6678 for FDG-PET, ACRIN 6678 for Volumetric CT, ADNI for MRI) into the protocol template. The group is also continuing work on refining the vetting criteria for proffered protocols and annotations and working on the IT infrastructure for the web-based searchable resource library of proffered protocols.

#### **CTSA IWG subgroup report: Cores/Education**

- Cores/Education PowerPoint presentation by Dr. Brian Reynolds and Dr. Katarzyna Macura

The CTSA Imaging Working Group Cores/Education Subgroup has as its goals:

- Defining an 'imaging core' and enhancing awareness of CTSA imaging cores
- Creating an inventory of imaging technologies
- Defining mechanisms to make imaging available to translational researchers
- Providing access to imaging experts
- Examining methods of providing guidance and education

A 15-question survey to address structure, expertise, and respondents' role in CTSA was sent by the subgroup to imaging contacts at all 38 CTSA sites in 2008. From a ranking of the most frequent responses by the 20 respondents, small workgroups have been formed to:

- Investigate educational programs' approaches related to clinical or translational imaging
- Identify best practices in providing review of imaging protocols
- Identify mechanisms of obtaining funding for imaging cores
- Create awareness and accessibility of the CTSA IWG and the imaging capabilities available to researchers
- Provide researchers with access to imaging expertise.

As a follow-up to the survey, the Cores/Education subgroup's continuing efforts will focus on consolidating the survey information, collecting protocols, flow charts, processes, educational programs and networking approaches from sites and publishing best practices. Information from sites will be compiled into a 'white paper' and publicized to the Imaging Working Group via the website, wiki and other mechanisms. Participation from additional CTSA sites and representatives is welcome and encouraged as the Cores/Education group moves to formalize the shared practices document; the group hopes that many sites and participants will be justifiably listed as corresponding or contributing authors.

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