NTR Face-to-Face Meeting

Location: Houston, Texas

Thursday and Friday 29-30th April 2010

Final Agenda

Mission of the Third NTR Meeting:

The mission of this third NTR meeting is to launch discussions among the NTR centers and Research Support Cores regarding methods of validation for multimodal imaging platforms.

Rationale

The primary goal of NTR is to seek a network-wide consensus on methods to optimize and validate the next generation of molecular imaging technologies to help reduce the threshold for their regulatory approval. As NTR transitions in this second year of funding from the development phase to translational concerns such as standardization and validation, the steering committee teleconference meetings have begun to focus on validation concepts and strategies. In addition, the roles of the research cores are focusing on means to generate consensus on requirements needed to validate these technologies.

This is the first NTR face-to-face meeting where the centers have been specifically tasked to present their strategies to validate their imaging platforms, and the research cores are tasked to fine-tune their research and related resources to meet these translational research challenges. The goal of this NTR meeting is to take the first steps toward developing a coherent validation strategy, and to develop a plan for the next NTR face-to-face meeting where this stragety will be presented to representatives of NCI, as well as to FDA, NIST, and the NTR industrial partners. Plans for consensus publications across the network are to be explored. The intent is to create publications to influence the FDA guidance documents for approval for multimodal imaging platforms, where it is anticipated that they may be categorized as "combined technologies".

Thursday April 29, 2010

7:30 Gathering

7:50 NCI Program: Overview of NTR meeting agenda

Larry Clarke, Ph.D. and Robert Nordstrom, Ph.D. Imaging Technology Development Branch Cancer Imaging Program of NCI

8:00 Industrial Perspective on Validation

Anne Smith, Siemens Michael Pashley, Philips

8:45 Session 1: NTR PI Center Presentations:

Research Progress and Validation Strategies for year 2-5.

25 Min presentation, 5 min discussion.

Session Chair: Robert Nordstrom

Goals are to cover research progress for first 5 minutes, and the remaining 20 minutes on each team's strategy to validate their imaging platform for the targeted cancer problem. The intent is to identify where the research cores can help accelerate translational goals and identify resources that may be needed.

8:45 Center #1: Washington University

Lihong Wang, Ph.D.

9:15 Center #2: University of Texas Health Science Center

Eva Sevick, Ph.D.

9:45 Center #3: University of Michigan

Thomas Wang, M.D. Ph.D.

10:15 Center #4: Stanford University

Christopher Contag, Ph.D.

10:45 Coffee Break

11:00 Session 2: Breakout Session:

Goals: Research Cores review of each team's validation strategy plans. Determine their requirements from each Core. Participants: Research Cores and center PI's.

12:00 **Lunch**

1:00 Session 3a: Detailed Case Report: Texas Validation Implementation 50 min presentation, 10 min discussion. Session Chair: Larry Clarke Goals: To review a case report from Texas on how to use the Sciport

software for the clinical trial setting, and to include a physical verification and clinical strategy validation strategy to provide traceability for all aspects of the translational research pipe line.

2:00 Coffee Break

2:30 Session 3b: Case Report (con't.): Texas Validation Implementation.

Session Chair: Larry Clarke

3:30 Wrap up discussions

4:00 End of first day

6:00 Dinner and Informal Discussions

Friday April 30, 2010

7:30 Gathering

8:00 Session 4: Research Support Cores: Progress to date and Plans for FY 2, Anticipated Needs FY 2-5.

Session Chair: Robert Nordstrom

20 minutes for each Core:

- Standards & Compliance
- Chemistry Probes & Guided Therapies
- Information Technology
- Instrumentation & Industrial Relations

• Validation & Clinical Studies

10: 00	Coffee Break
10:30	Session 5: Panel Discussion: Research Core Evaluations of Validation efforts: Moderator Larry Clarke
	Standards & Compliance Chemistry Probes & Guided Therapies Information Technology Instrumentation & Industrial Relations Validation & Clinical Studies
11:30	Lunch
12:30	NTR SC Meeting: NTR Management and Organizational Issues NTR PI's and Co-I's, Program Staff
1:15	Action Items and Wrap Up
1:30	End Meeting