

**The MGH-HST Center for Biomarkers in Imaging**

Semi-Annual Meeting

1 December 2005

Hilton Alexandria Old Town, Alexandria, VA

(1767 King Street, Alexandria)

*8:00 – 8:30 Registration, Continental Breakfast**8:30 – 8:45 Introductions and Welcome**Sorensen/Pien**8:45 – 11:30 Validation of Imaging Biomarkers*

Validation of biomarkers as surrogate endpoints involves the collection and analysis of a significant amount of evidence in a variety of settings. In this session we will look at different frameworks for validation, and examine several case studies including tumor measurements, perfusion measurements, and FDG-PET. We will provide an overview of the evidence for and against particular imaging biomarkers, and suggest the additional evidence necessary to move towards surrogate endpoints.

8:45 – 9:45	Validation frameworks, tumor measurements and other initiatives (ACRIN, UPICT, NCI, PhRMA, etc.)	Pien (MGH)
9:45 – 10:15	FDG-PET for GI stromal tumors	Collins (NIH)
10:15 – 10:30	Break	
10:30 – 11:00	New biomarkers to move towards surrogacy	Hargreaves (Merck, tentative)
11:00 – 11:30	Biomarker validation from regulator's perspective	Mills (FDA)
11:30 – 11:50	Discussion of other issues impacting validation	ALL
11:50 – 12:00	Wrap-up, next steps	Pien/Sorensen (MGH)

*12:00 – 1:30 Network Lunch**1:30 – 5:00 Approval and Commercialization of Molecular Imaging Agents*

In this session we begin to identify issues relevant to the approval and commercialization of molecular imaging agents, with an eye towards holding a workshop in 2006 which addresses the question "why are there so few molecular imaging agents?" We intend to address these issues from a number of different perspectives, with participation by both CBI membership and invited outside experts.

1:30 – 2:00	Brief overview	Sorensen (MGH)
2:00 – 2:20	Economics of imaging agent development	Nunn (Bracco)
2:20 – 4:45	Issues	ALL
	Imaging agent developers	
	Regulatory perspective	
	NIH/NCI perspective	
	Users community	
4:45 – 5:00	Wrap-up, next steps	Sorensen (MGH)

*5:00 Meeting adjourn**Hotel Information:*

A block of rooms has been reserved at the Hilton Alexandria Old Town for this conference. Please call 1-800-HILTONS or 703-837-0440 and ask for the "Center for Biomarkers in Imaging" block of rooms by 4 November 2005.