MR WORKSHOP ON TRANSLATIONAL RESEARCH IN CANCER – TUMOR RESPONSE

Hyatt Regency ♦ Bethesda, MD

November 22-23, 2004

Sponsored by: Cancer Imaging Program, National Cancer Institute (NCI)

Organizing Committee:

Michael Garwood (University of Minnesota)
Jeffrey Evelhoch (Amgen, Inc.)
Michael Knopp (Ohio State University)
Daniel Vigneron (University of California, San Francisco)
Guoying Liu (Cancer Imaging Program, NCI)
Anne Menkens (Cancer Imaging Program, NCI)
Laurence Clarke (Cancer Imaging Program, NCI)
Daniel Sullivan (Cancer Imaging Program, NCI)

November 22, 2004 - Morning		
Time	**Topics / Sessions**	**Chairs/Speaker(s)**
7:30 – 7:45	**Registration--Sessions in Haverford-Baccarat Rooms**	
7:45 – 8:00	**Introduction:**	**Daniel Sullivan (Cancer Imaging Program, NCI)**
8:00 - 12:00	***Session I:*** **MR in Clinical Assessment of Anti-Tumor Therapies** ***Overview/Status Check: What's Been Done, and Where Are We Now? How and Where Do the MR Methods Fit in Anticancer Drug Assessment, or Guiding/Monitoring Radiation Therapies?***	**Co-Chairs: Jeffrey Evelhoch (Amgen, Inc.), Michael Garwood (University of Minnesota)**
8:00 - 9:40	**1. Perspectives**	
8:00 - 8:20	• **Oncologist's Perspective: DCE-MRI for Assessing Cancer Therapeutic Response**	**Patricia LoRusso (Wayne State University)**

8:20 - 8:40	• **Oncologist's Perspective: MRS for Assessing Cancer Therapeutic Response**	**Douglas Yee (University of Minnesota)**
8:40 - 9:00	• **Pharma Perspective:** How do Pharmaceutical Industries see the Use of MR as a Biomarker for Oncologic Drug Development	**Susan Galbraith (Bristol-Myers Squibb Company)**
9:00 - 9:20	• **FDA Perspective:**	**Jerry Collins (FDA)**
9:20 - 9:40	• **CTEP Perspective:** Summary of CTEP Oncologic Trials Where MR Is Involved; What Does CTEP Expect of MRI and MRS?	**Jeffrey Abrams (Cancer Therapy Evaluation Program, NCI)**

9:40 - 9:55 Break

9:55 - 11:15 2. DCE-MRI

9:55 - 10:15	• **Overview**	**Jeffrey Evelhoch (Amgen, Inc.)**
10:15 - 10:35	• **DCE-MRI in Tumor Treatment Response**	**Michael Knopp (Ohio State University)**
10:35 - 10:55	• **DCE-MRI in Clinical Trials - the CRUK Experience**	**Martin Leach (Cancer Research UK and University of London)**
10:55 - 11:15	• **DCE-MRI in Monitoring Response to Radiation Therapy**	**Nina Mayr (Ohio State University)**

11:15 - 12:15 3. MRS

11:15 - 11:35	• **Overview**	**Michael Garwood (University of Minnesota)**
11:35 - 11:55	• **MRS in Monitoring Drug Therapy**	**Jason Koutcher (Memorial Sloan-Kettering Cancer Center)**
11:55 - 12:15	• **MRS in Guiding/Monitoring Therapy Response to Radiation**	**Daniel Vigneron (University of California, San Francisco)**

12:15 - 1:30 Lunch (on your own)

November 22, 2004 - Afternoon		
Time	**Topics / Sessions**	**Chairs/Speaker(s)**
1:30 - 5:00	***Session II:*** **Panel Discussion: in Haverford-Baccarat Rooms** ***Design of Multicenter Clinical Trials-Technical and Implementation Issues; Development of a Multicenter Clinical Trial Protocol; Consensus***	**Co-Chairs: Jeffrey Evelhoch (Amgen, Inc.), Michael Garwood (University of Minnesota)**
1:30 - 1:45	**1. Status Summary**	**Jeffrey Evelhoch and Michael Garwood**
1:45 - 3:15	**2. DCE-MRI and MRS--Clinical Issues** Panelists: Daniel Vigneron, Michael Knopp, Nina Mayr, Susan Galbraith, Patricia Lorusso, Jeffrey Abrams, Gary Kelloff (NCI), Jason Koutcher, Douglas Yee, Jerry Collins, Gregory Curt (AstraZeneca), Antonio Wolff (Johns Hopkins University)	Moderators: Jeffrey Evelhoch and Michael Garwood
1:45 - 2:00	**Imaging as biomarkers for predicting early response, recurrence and survival outcomes - ACRIN Experiences** **• Topics for discussion:** How do we validate DCE-MRI and MRS? What should a uniformly accepted validation study look like for DCE-MRI? For MRS? What should be in there? What are the hurdles affecting implementation in clinical trials? Use of MR for patient selection in therapeutic trials Database design, development, benchmark modeling, and data processing methods	Daniel Vigneron/John Kurhanewicz (University of California, San Francisco)
3:15 - 3:30	**Break**	
3:30 - 5:00	**3. Two Parallel Break Out Sessions, No. 1 Technical Issues for DCE-MRI or No. 2 MRS** **DCE-MRI Panel: in Haverford-Baccarat Rooms**	

Panelists: Michael Knopp, Thomas L. Chenevert (U. of Michigan), Peter Choyke (NCI), Edward ackson (UT M.D. Anderson), Robert Gillies (U. of Arizona), Martin Leach, Anwar Padhani (Mount Vernon Hospital, London), Mark Rosen (U. Penn.), Gregory Sorensen (Harvard Medical School), Charles S. Springer (Oregon Health and Science University), Patricia Cole (Novartis), Michael Tweedle (Bracco), Adrian Knowles (GE), Milind Dhamankar (Siemens)

Chair: Jeffrey Evelhoch

MRS Panel: in Waterford-Lalique Rooms

Panelists: Daniel Vigneron, John Griffiths (Cancer Research UK), Michael Jacobs (Johns Hopkins U.), John Kurhanewicz (UC San Francisco), Lester Kwock (U. of North Carolina), Sarah Nelson (UC San Francisco), Douglas Kelley (GE), Peter Martin (Philips), Teresa McShane (Pfizer), Stefan Roell (Siemens)

Chair: Michael Garwood

- **Topics for discussion in breakout session:**

Examine technical issues
What needs to be done to meet clinical requirements for multi-site studies?
Is there consensus on the maturity of the methods?
Developing and improving methods, data analysis, algorithms, field strength, coils, gradients, standardization and consensus

November 23, 2004 - Morning and Afternoon		
Sessions in Haverford-Baccarat Rooms		
Time	**Topics / Sessions**	**Chairs/Speaker(s)**
8:00 - 8:35	**Overview: Diffusion MRI in the Assessment of Cancer Therapeutic Response**	
8:00 - 8:20	Overview of Diffusion MRI	**Thomas Chenevert (University of Michigan)**
8:20 - 8:35	Discussion	
8:35 - 10:15	**Device and Pharmaceutical Manufacturers Panel Discussion**	
	Panelists: Douglas Kelley (GE), Stefan Roell (Siemens), Adrian Knowles (GE), Peter Martin (Philips), Milind Dhamankar(Siemens), Patricia Cole (Novartis), Michael Tweedle (Bracco), Gregory Curt (AstraZeneca), Teresa McShane (Pfizer), Donald Williams (Merck)	**Moderator: Michael Knopp**
8:35 - 8:50	Public-Private Partnerships **• Topics for discussion:** How do you manage upgrades without impacting protocols? How can we achieve support for multi-vendor standardized MR sequences? How to enable sharing/use of “research” sequences within clinical trials and globally? What are the differences in the vendor environment between “Investigator initiated Trials” and “Pharma sponsored trials” ? - “technical,” as well as vendor specific “legal” policies - Standardized acquisition protocol such as push-button T1-Mapping What is the vendor’s vision/strategy to facilitate post acquisition analysis of A), Imaging; B), Spectroscopy?	Laurence Clarke (Cancer Imaging Program, NCI)
10:15 - 10:30	**Break**	
10:30 - 12:00	**Session II Continued: DCE-MRI and MRS breakout sessions reconvene** • To Finalize the Demonstration Protocol and Consensus Report	

12:00 - 1:15 Lunch (on your own)

1:15 - 4:00 ***Session III: Summary Discussion*** **- Looking Forward - Prospects of MR in the Assessment of Cancer Therapeutic Response**

1.Presentation of DCE-MRI Consensus Report	**Jeffrey Evelhoch**
2.Presentation of MRS Consensus Report	**Michael Garwood**
3.Group Discussion on the Consensus Reports	

4 **Response and Comments From:**

Workshop Organizers, Oncologists, CTEP, Pharma (What opportunities do they see for supporting the development and application of MR-Biomarkers for Oncologic Drug Development?), Device Companies, ACRIN, FDA

Summary and Closing Remarks: **Jeffrey Evelhoch and Michael Garwood**

Workshop Adjourns