



The USC Biomedical Imaging Science Initiative

Workshop on

Imaging-based Tools for Target Pharmacokinetics/Pharmacodynamics: Role in Drug Development and in Drug Monitoring

Location: Pasadena Hilton Hotel

168 South Los Robles Avenue, Pasadena, California 91101

Monday, January 22, 2007

6:00 – 8:00 pm **Registration**

Tuesday, January 23

7:00 am **Continental Breakfast and Registration**

8:00 am **Welcome**

Walter Wolf, PhD

Chair, Biomedical Imaging Science Initiative, USC

8:15-10:30 am **Inaugural session: What is working and what is not working in the use of pharmacokinetic imaging in drug development and in clinical studies**

Chair/Rapporteur: Daniel Sullivan, MD

The NCI Cancer Imaging Program: its accomplishments and its unmet needs

Daniel Sullivan, MD

Associate Director, Cancer Imaging Program, National Cancer Institute, Bethesda, MD

The FDA Critical Path: current status and models for collaborations

Wendy Sanhai, PhD

Senior Scientific Advisor, Office of the Commissioner, US Food and Drug Administration, Rockville, MD

The UK Pharmacodynamic/Pharmacokinetic Technologies Advisory Committee: its accomplishments and its unmet needs

Eric Aboagye, PhD

Professor of Cancer Pharmacology & Molecular Imaging, Imperial College London, United Kingdom

A proposed systems approach to pharmacokinetic and pharmacodynamic studies that is possible using noninvasive imaging

Walter Wolf, PhD

Professor of Pharmaceutical Sciences and Chair, Biomedical Imaging Science Initiative, USC

10:45 am – 12:00 noon

Principles and roadblocks in the use of imaging for PK/PD studies

Chair/Rapporteur: David Z. D'Argenio, PhD

Can imaging methods expand our understanding of Pharmacokinetics and Pharmacodynamics?

Ruediger Port, MD

Senior Scientist, Genentech Inc, South San Francisco, CA

What are the main instrumental issues in generating PK/PD measurements?

Wilfried Loeffler, PhD

Head of R&D, Siemens Medical Solutions Molecular Imaging Group, Knoxville, TN

12:00 – 1:00 pm

Lunch

1:00 - 3:15 pm

Principles and roadblocks in the use of imaging methods for PK/PD studies

Chair/Rapporteur: Andrew Raubitschek, PhD

Chair, Cancer Immunotherapeutics & Tumor Immunology

Beckman Research Institute, City of Hope National Medical Center, Duarte, CA

Nuclear Imaging (PET, SPECT, w/o CT): Past, Present and Future in PK/PD

Henry Van Brocklin, PhD

Professor of Radiology, Director of Radiopharmaceutical Research, Center for Molecular and Functional Imaging, UCSF, CA

Fundamental Differences of Pharmacokinetic Models for MRI and Nuclear Medicine

Charles Springer, PhD

Professor and Director, Advanced Imaging Research Center, Oregon Health and Science University, Portland, OR

Optical and other Imaging methods: Past, Present and Future in PK/PD

Bruce Molitoris, PhD

Professor and Director, Indiana Center for Biological Microscopy, University of Indiana, Indianapolis, IN

3:30 - 5:45 pm

Principles and roadblocks in the use of imaging methods in PK/PD in drug development studies

Chair/Rapporteur: Robert Gillies, PhD

Imaging in Drug Development – an academic perspective

Robert Gillies, PhD

Professor and Director, Advanced Research Institute for Biomedical Imaging, University of Arizona, Tucson, AZ

Imaging in Drug Development – a perspective from the imaging industry

Jean Luc Vanderheyden, PhD

Global Molecular Imaging Leader, General Electric Healthcare, Waukesha, WI

Imaging in Drug Development – a perspective from the pharmaceutical industry

Raymond E. Gibson, PhD

Senior Research Scientist, Merck Research Laboratories, Rahway, NJ

6:30 pm

Dinner with presentations and discussion on:

Imaging in pharmaceutical research: how can we deliver more benefit to the public and get more bang for our buck?

Alexander Capron, LLB

University Professor, Scott H. Bice Chair in Healthcare Law, Policy and Ethics, and Professor of Law and Medicine, University of Southern California, Los Angeles, CA

Belinda Seto, PhD

Deputy Director, National Institute of Biomedical Imaging and Bioengineering, Bethesda, MD

Mauro Ferrari, PhD

Professor, Brown Institute of Molecular Medicine, University of Texas Health Sciences Center, Houston, TX

Wednesday, January 24

7:00 am

Continental Breakfast

8:00-9:30 am

Principles and roadblocks in the use of imaging methods in clinical PK/PD studies

**Chair/Rapporteur: Patricia Cole, PhD, MD and
Patrick M. Colletti, MD**

*Professor of Radiology, Pharmaceutical Sciences and
Biokinesiology, USC, Los Angeles, CA*

Imaging in clinical studies – an academic perspective

Peter Conti, MD, PhD

Professor of Radiology, Biomedical Engineering and Pharmacy, USC, Los Angeles, CA

Imaging in clinical studies – a perspective from the imaging industry

Peter Martin, PhD

Director Business Development, Molecular Imaging, Philips Medical Systems

Imaging in clinical studies – a perspective from the pharmaceutical industry

Patricia Cole, PhD, MD

Senior Director and Head, Imaging Programmes, Eisai Medical Research, Ridgefield Park, NJ

9:45-11:30 am

Economic, educational and other roadblocks in the use of imaging methods in PK/PD

Chair/Rapporteur: Peter Conti, MD, PhD

The Role of Open Source Imaging Toolkits in the Development of Dynamic Imaging Biomarkers

Rick Avila, MS

Director of Medical Applications, Kitware Inc, Clifton Park, NY

Economic considerations in the use of noninvasive imaging methods in drug development and drug monitoring

Gurinder Shahi, MD, PhD

Keck School of Medicine, University of Southern California, Los Angeles, CA

Educational needs in the expanded use of noninvasive imaging methods in drug development and drug monitoring

Panel Speakers:

Sarah Hamm-Alvarez, PhD, *Professor and Chair, Pharmacology and Pharmaceutical Sciences, University of Southern California, Los Angeles, CA*

David Z. D'Argenio, PhD, *Professor, Biomedical Engineering, University of Southern California, Los Angeles, CA*

Cary A. Presant, MD, FACP, *Wilshire Oncology Medical Group, West Covina, CA*

11:30 am **Report from working groups and review of recommendations**

12:30 pm **Adjourn meeting**