

**KEYNOTE PRESENTATIONS FROM:**

Ellen Feigal, Director of the Division of Cancer Treatment and Diagnosis,  
**National Cancer Institute (NIH)**  
 Antonio J. Grillo-Lopez, M.D., Chair,  
**Neoplastic and Autoimmune Disorders Research Institute;**  
 Former Chief Medical Officer and Senior Vice President,  
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**CHOOSE FROM 2 PRE-CONFERENCE WORKSHOPS:**

**Primer:**

**A. Why, When and How to Image**

**B. Operationalize RECIST — Incorporate Independent Endpoint Review Charters in Oncology Trials**

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**C B I ' S W E S T C O A S T F O R U M O N**

# MEDICAL IMAGING FOR ONCOLOGY CLINICAL TRIALS

**EXPLORE VARYING IMAGING MODALITIES FOR CLINICAL TRIAL APPLICATION AND ACCELERATE DRUG DEVELOPMENT WITH ADEPT IMAGE RESPONSE EVALUATION**

**April 22-23, 2004 – Hilton San Diego Mission Valley Hotel – San Diego, CA**

- Leverage the capability of imaging as a decision-making tool during early drug development
- Analyze and translate data from animal studies to human applications
- Evaluate shortcomings, applications and cost between PET, CT and MRI
- Apply new optimal imaging techniques to track cell changes
- Use contrast agents to heighten accuracy of imaging and monitor response to interventions
- Cut costs and accelerate early development for faster go/no-go decisions with automated quantitative image analysis
- Extract value from imaging through quality protocols, data acquisition and robust analysis tools
- Gain critical insights into clinical applications of the International Working Group Response Criteria for Non-Hodgkin's Lymphoma
- Hear about the latest advances in imaging hardware and software

**PLUS!**

Learn how to use imaging endpoints, such as time to progression, to seek accelerated approval

**AND — TWO CASE STUDIES:**

- Benchmark against the strategies and methods used for staging lymphoma during the clinical trial for Bexxar™
- Evaluate the use of imaging as an investigational endpoint of tumor response in the Velcade trial

A. **A PRIMER:**

**WHY, WHEN AND HOW TO IMAGE**

Introducing imaging technologies into clinical trials presents many new challenges and opportunities to clinical scientists in the pharmaceutical and biotechnology industry. Deciding whether or not to image, strategically developing an effective protocol and understanding the limitations and advantages associated with imaging modalities are all integral factors considered in this workshop.

7:30 *Registration and Continental Breakfast*

8:30 *Workshop Leaders' Welcome and Opening Remarks*

**I. To Image or Not to Image**

- Is the cost of imaging greater than the benefit when incorporated into clinical trials?
- What is required to translate a diagnostic imaging procedure into a tool that will aid clinical trial performance?

**II. Designing a Goal-Driven and Effective Protocol**

- Logistics and tactics for implementing imaging
- Selecting the best imaging technology tools for a customized clinical trial
- The issue of multi-site performance of trials
- Academic research organization vs. contract research organizations

**III. Strategies for Managing Partnerships with Imaging Core Labs**

- Defining and managing expectations for the sponsor and core lab
- Establish meaningful timelines and ensure conformity with deadlines

**IV. Technology Basics — Which Modality to Use and Why**

- Assess the basic pros & cons of the imaging modalities
- Determine which technology will garner optimal data for the unique needs of your study

12:00 *Close of Workshop*

*There will be a 30-minute networking and refreshment break at 10:00 am*

**— About Your Workshop Leaders —**

**Michele Britton, M.A.**, Manager of Clinical Operations, **Corixa Corporation**, has over 12 years experience in clinical research, including clinical trial management in a number of biotech/pharmaceutical companies. Ms. Britton's current responsibilities at Corixa Corporation include global clinical research management of cross-functional study teams, protocol design and strategic planning, program oversight of contract research organizations, and supervision of image management and bio-database submission. She completed her Master of Arts at John F. Kennedy University and Bachelors of Science at Texas A&M University.

**Manish Kothari, Ph.D.** is the Vice President of Scientific Client Services at **Synarc**. Dr. Kothari's doctorate is in bioengineering from Cornell University as part of the Cornell University-Hospital for Special Surgery Program in Biomedical Engineering, and did his postdoctoral work at the Magnetic Research Science Center, University of California, San Francisco. Dr. Kothari has considerable experience in the areas of medical image analysis, and design of image acquisition protocols for clinical trials, from the quantification of trabecular architecture in osteoporosis and osteoarthritis to the assessment of brain damage in shaken baby syndrome and programming. His postdoctoral work linking high resolution ex-vivo imaging of bone to in-vivo MR imaging has helped develop robust in-vivo quantitative measures of trabecular bone quality. He has a number of peer-reviewed scientific publications and presentations at scientific meetings, and has authored a number of imaging protocols for both animal research and human clinical trials. Over the last decade, Dr. Kothari has focused on developing advanced computer-assisted methods and image acquisition techniques for the assessment of various diseases and injuries. Previously, he was the Vice President of Medical Imaging Technology of Synarc where he was responsible for integrating image analysis with image acquisition, and thereby ensuring that the scientific data delivered to the client is of the highest quality.

**Ted Gastineau** is CEO and co-founder of **Beacon Bioscience, Inc.**, a high-tech medical informatics company specializing in medical imaging for drug development. In this role he is responsible for leading a variety of technical and strategic initiatives for global pharmaceutical/biotech companies involved in the development of therapeutic and diagnostic products for Oncology, Cardiovascular Disease and CNS Disorders. From 1995 through 2000, Mr. Gastineau co-founded and served as President of **Intelligent Imaging, Inc.**, a high-tech pharmaceutical research company specializing in medical imaging technology acquired by Quintiles, Inc. Mr. Gastineau has held academic positions with the **University of Maryland, The Johns Hopkins School of Medicine, Cambridge University and The Smithsonian Institution.**

**Ali Guermazi, M.D.** is a board certified radiologist with expertise in oncology particularly Hodgkin's and non-Hodgkin's lymphoma hematology, neuroradiology and musculoskeletal disorders. At **Synarc**, Dr. Guermazi is Director of Clinical Research and an expert reader of medical images for clinical trials. Dr. Guermazi has a medical degree from the University of Sfax, Tunisia in 1989. He completed his internship in Radiology at the University of Paris V. He has medical certificates in Neuroradiology, Imaging in Sports Medicine, Central Nervous System Diseases, and Vascular Non-Interventional Radiology from the University of Paris VI. Dr. Guermazi is the recipient of many scientific awards including the Visiting Scholar Program of the French Society of Radiology in 1997 and the European Association of Radiology Exchange Program in 1996. He has written over 50 medical and scientific articles and 13 book chapters. He also edited two text books, and lectures regularly at scientific and medical congresses around the world.

## B. OPERATIONALIZE RECIST — INCORPORATE INDEPENDENT ENDPOINT REVIEW CHARTERS IN ONCOLOGY TRIALS

Oncology trials are increasingly relying on non-survival endpoints such as time-to-progression and response rate to demonstrate product efficacy. These subject endpoints may bring significant variability, thus requiring the need for Independent Endpoint Review Panels to review data in a blinded manner. Gain an understanding of the challenges and opportunities in implementing an independent review charter for Oncology trials, while also learning the optimal process for modifying response criteria for a specific protocol.

7:30 *Registration and Continental Breakfast*

8:30 *Workshop Leaders' Welcome and Opening Remarks*

### I. RECIST and the Independent Review Charter (IRC)

- Closing the gaps in the RECIST criteria
- Role and development of the independent review charter

### II. Planning the Trial with an Independent Endpoint Review

- Study start-up & planning
- Training the investigator site
- Standardize image acquisition and ensure quality

### III. Image and Data Processing Considerations

- Masking and blinding imaging data
- Redaction of clinical data
- Quantitative image analyses
- Image archival and storage

### IV. Independent Review Process

- Selecting the independent reviewers
- Panel training
- Sequential data review process
- Review systems and tools
- Maintaining regulatory compliance

12:00 *Close of Workshop*

*There will be a 30-minute networking and refreshment break at 10:00 am*

### — About Your Workshop Leaders —

**Richard Jacobs, M.D., M.H.A.**, Vice President and Medical Director of Medical Diagnostics, **Perceptive Informatics**. Dr. Jacobs' overall medical responsibility includes managing the imaging component of worldwide clinical trials researching: cardiology, hematology, neurology, oncology, osteoporosis, diagnostic agents and medical devices. Dr. Jacobs maintains his academic appointment as Assistant Professor of Radiology at the University of Massachusetts. Prior to joining Perceptive, Dr. Jacobs served as Chairman of Radiology and Diagnostic Imaging at **Memorial Health Care**.

**Craig Lipset**, Senior Director for Strategic Development, **Perceptive Informatics, Inc.** is Senior Director for Strategic Development at Perceptive Informatics, Inc. He is responsible for consulting and advising the bio-pharmaceutical industry on the successful implementation of imaging and other technologies in their clinical development programs. Prior to Perceptive, he served as a consultant for several leading pharmaceutical companies. In this role Mr. Lipset evaluated the feasibility for initiating several multi-national protocols. He also worked as an epidemiologist with a pharmaceutical consulting firm, developing pharmacoeconomic models to assess potential markets for new therapeutics. Mr. Lipset received his undergraduate degree from Brandeis University in Waltham, MA, and his Masters in Public Health in Epidemiology from Columbia University in New York, NY.

# MAIN CONFERENCE

**Day One — Thursday, April 22, 2004**

12:00 *Main Conference Registration*

1:15 *Chairman's Welcome and Opening Remarks*

Joel Feinblatt, Ph.D., Associate Medical Director, Medical Imaging,  
**Perceptive Informatics**

*Dr. Feinblatt has 15 years of experience in drug development including imaging services, project management and clinical research. He has covered projects in a wide range of therapeutic areas. Prior to joining Perceptive, he was Manager of Project Services at Princeton Radiology Associates (RADPHARM) where he led the project management group at this core-imaging laboratory, with responsibility for over 30 projects in the oncology area. Dr. Feinblatt also served as Senior Scientific Director and Head of the Osteoporosis Research Center at Covance, Inc. where he was responsible for the imaging aspects of several major trials. He also served several years as International Project Manager and Associate Clinical Director at Novartis/Sandoz Pharmaceuticals. Before joining the pharmaceutical industry, Dr. Feinblatt was Associate Professor of Physiology at both the University of Massachusetts and Tufts Medical Schools. He received his Ph.D. in Physiology from the University of Pennsylvania and his Bachelor of Science in Biology from Brooklyn College.*

## NCI KEYNOTE ADDRESS

1:30 **The NCI and Imaging — Intersecting Scientific Opportunity with Clinical Need**

The National Cancer Institute has identified imaging as an extraordinary opportunity for investment. The opportunity is the ability to detect, through imaging, the molecular changes associated with a tumor cell that will improve our ability to select and stage tumors, select appropriate treatments, monitor the effectiveness of treatment and determine prognosis. NCI's goal is to move imaging into the early role of identifying pathways of disease pathogenesis and the discovery and development of new diagnostic and therapeutic interventions.

- NCI's role in catalyzing and fostering cancer imaging
- Specific initiatives and illustrative examples in probe development, biomarkers and clinical trials
- Interactions with FDA and CMS to foster technology development and the lessons learned to date
- Financial investment in imaging
- Future directions

Ellen Feigal, M.D., Director, Division of Cancer Treatment and Diagnosis, National Cancer Institute, **National Institutes of Health**

*Dr. Feigal received her B.S. in Biology and an M.S. in Molecular Biology and Biochemistry at the University of California, Irvine. She subsequently received her M.D. in Medicine from the University of California, Davis, and completed her residency in Internal Medicine at Stanford University. She completed her fellowship in Hematology/Oncology at the University of California, San Francisco (UCSF). She was faculty at UCSF and then at the University of California, San Diego, before joining the National Cancer Institute in 1992. She was made Deputy Director in 1997, and has held her current position since December 2001. The Division is responsible for many broad-reaching research programs such as drug discovery and development, cancer diagnostics, radiation biology, biomedical imaging, clinical trials and biometrics.*

2:15 **Translational Imaging — Improve Transitioning in Preclinical, Phase I and Phase II of Oncology Trials**

Ascertaining the appropriate data at the right point in clinical testing can save in time and money. Within early drug development lies the opportunity for imaging to aid in transitioning. Learn to leverage the capabilities of imaging as a decision making tool during early drug development in order to expedite your cancer clinical trial.

- Identify endpoints to be measured in both preclinical and clinical stages of research
- Analyze and translate data from animal studies to human applications using medical imaging
- Recognize and resolve the typical issues early on in your trial
- Monitor and measure anti-angiogenesis, metabolism, proliferation and apoptosis
- Design a Phase I study that effectively implements imaging for toxicology and efficacy indications
- Practical examples of imaging utility at the various stages of clinical oncology trials

Susan Galbraith, M.B., B.Chir., Ph.D., Director Clinical Discovery, Oncology, **Bristol-Myers Squibb**

3:00 **Medical Imaging Agents in Oncology Trials — Current Challenges and Future Perspectives**

There is an increase interest in the use of imaging results as an endpoint in oncology trials. The use of contrast agents is often needed to increase the accuracy of the imaging methods, as well as to monitor response to interventions. This session covers practical aspects of the design and conduct of oncology trials using medical imaging agents, both from the efficacy and safety point of view.

- Complexities and challenges in the design and conduct of oncology trials using medical imaging agents — Practical efficacy and safety considerations
- Novel uses of medical imaging agents in oncology — CT, MR and ultrasound imaging of cancer
- Perfusion imaging in assessment of extent of malignant diseases and monitor response to treatment
- Design of new biomarkers in cancer imaging

Judith Murphy, M.D., Executive Director of Corporate Medical Affairs and Planning, **Bracco R&D**

3:45 *Networking & Refreshment Break*

4:15 **Imaging Endpoints — Employ Blinded Read Methodologies**

When medical imaging is used as an endpoint in oncology trials, the methodology for assessment has a different requirement to that of the used at the trial site for patient management. The need for blinded reads with defined criteria requires a change in paradigms for the radiologist who is used to evaluating image sets on a time-point by time-point basis. There are several methodologies that can be employed and will be presented, including:

- Conducting film reads
- Paper assisted masked reads
- Computer assisted masked reads
  - \* multiple session reads
  - \* step-wise un-blinding
- Confirmation read verses independent read

Colin Miller, Ph.D., Vice President, Business Development, **Bio-Imaging Technologies, Inc.**

**Educational Grant  
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5:00 **The Revolutionary Impact of Positron Emission Tomography Imaging — PET Scans Further the Capacity to Measure Response to Cancer Treatments**

PET scanning produces quantitative and reproducible computerized images of chemical and metabolic changes within tissue, and has been shown to be a remarkably accurate and insightful tool during clinical trials. Delegates learn the current status of PET imaging, its applications to their oncology clinical trials and the future applications of this novel technology.

- PET overview — What it is, how it works and when to apply to research efforts
- Maximize PET derived data — Analyze and interpret PET data effectively
- Using PET in early development of investigative new therapeutics
- Develop new treatment strategies based on patient's response to initial therapy
- PET versus CT or MRI — The advantages, shortcomings, applications and costs
- Overcome the challenges in utilizing PET imaging for developing new endpoints in Oncology trials
- Future prospects of PET technology

Abass Alavi, M.D., Professor of Radiology,  
University of Pennsylvania

5:45 *Close of Day One*



5:45-6:45 **Wine & Cheese Networking Reception**  
Join colleagues and friends in a relaxed setting.

**Day Two — Friday, April 23, 2004**

7:30 *Continental Breakfast Hosted by:* 

8:00 **Day Two Chairman's Review of Day One**  
Donald Rosen, M.D., Co-CEO and Chief Strategy Officer, RadPharm  
*Dr. Rosen has practiced as a diagnostic radiologist in Princeton, N.J. since 1990. Prior to that he was in private practice in Orange County, CA. As a member of Princeton Radiology Associates he co-founded RadPharm in 1998. He has lectured at many Pharmaceutical and Oncology meetings about the uses of diagnostic imaging in Oncology clinical trials. He is on the board of the American Cancer Society and the Breast Cancer Resource Center in Princeton. He received his B.A. from the University of Pennsylvania and his M.D. from the University of Cincinnati.*

8:15 **Targeted Cytostatics Demand Diagnostics**  
The advent of cytostatics targeting overexpressed peptides in tumors is a boon to the medical oncologists' pharmacopeia. As the list of therapeutic options grow, these oncologists need to do more than make the initial diagnosis and choose one or a cocktail of therapeutics tailored to expression in a biopsy of the primary tumor pre-treatment. They will need to confirm therapeutic benefit or switch therapy early in the course of treatment. Furthermore, as cytostatic therapy becomes chronic they



**CASE STUDY**

will need to re-confirm treatment benefit. These concepts need to be incorporated into current drug development plans by inclusion of appropriate biomarkers, which further enhance the value proposition for the pharmaceutical industry by increasing response rates. This session explores:

- Tracer development in MR and PET
- Advances in imaging hardware
- Advances in imaging software
- IT enablers of therapeutic decisions based on outcomes

Richard Frank, M.D., Ph.D., Chief Clinical Scientist in Advanced Technologies, Molecular Medicine and Biotechnology, **GE Global Research**

9:00 **Integrated PET+CT-based Response Classification for Non-Hodgkin's Lymphoma (NHL)**

Hear the findings and insights gained from a study done to determine whether FDG-PET+CT would result in a more accurate response classification compared with CT alone in patients with NHL. In this session, learn how this study challenges the current paradigm in response assessment of patients with NHL and suggest that PET/CT-based response classification may become the new standard for NHL.

- International Workshop Criteria vs. PET+CT-based response designations, such as:
  - \* complete response (CR)
  - \* unconfirmed CR (Cru)
  - \* partial response (PR)
  - \* stable disease (SD)
  - \* progressive disease (PD)
- Response designations that accurately reflect expected outcome in aggressive NHL
- The implications of the results of this unique study

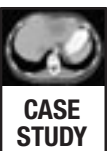
Malik Juweid, M.D., Division of Nuclear Medicine, Associate Professor of Radiology, **University of Iowa Hospitals and Clinics**

9:45 **Hear Strategies and Methods Used for Staging Lymphoma During the Clinical Trial for Bexxar™**

Bexxar™ (tositumomab/iodine 131I-tositumomab) is radioimmunconjugate-targeting CD20, which is an effective therapy single agent for the treatment of B-cell NHL. This unique case study reveals the trial strategy, results and lessons learned from the development of Bexxar™ from one of the leading trial facilitators. In this session, learn:

- Background and rationale of the Bexxar™ trial
- The role of imaging in the Bexxar™ clinical trial
- Response criteria applied to the Bexxar™ trial
- Optimizing the therapy effectiveness with imaging
- Patient-optimized dosing method utilized with Bexxar™
- Future directions in the development of Bexxar™

Andrew D. Zelenetz, M.D., Chief, **Lymphoma Service**; Head, Hematology Laboratory, **Memorial Sloan Kettering Cancer Center**



**CASE STUDY**

10:30 *Networking & Refreshment Break*

11:00 **Accelerate Speed and Productivity of Preclinical and Clinical Development with Automated Quantitative Image Analysis**

Imaging presents substantial opportunities for determining the efficacy of oncology compounds earlier in the development process. Imaging can be used to both make earlier go/no-go decisions as well as provide support for Phase III registration submissions. However, the ability to extract value from imaging is entirely dependent on the quality of underlying imaging protocols, the quality of image acquisition and the quality of the analysis tools applied.

- Raise the quality of imaging protocols and data acquisition used in clinical development
- Automate quantitative image analysis in Oncology — structural and perfusion imaging
- Lower cost and accelerate early development for earlier go/no-go decisions
- Improve precision of RECIST and WHO criteria through automation

Mikael Totterman, Chief Operating Officer, VirtualScopics LLC

11:45 **Optimize Application of RECIST Criteria**

Response Evaluation Criteria In Solid Tumors, RECIST, was implemented in an effort to standardize the methods used to assess a cancer patient's response to treatment. Effectively implementing RECIST criteria in clinical trials may achieve greater standardization and increased efficiency. Learn the practical methods of implementing RECIST in your protocol and standardizing imaging assessment at the investigator site and in the Imaging Core Lab setting.

I. **RECIST Definitions**

- Background
- Definitions of response classifications

II. **Applying and Standardizing RECIST for Clinical Trials**

- Technical scanning parameters and effect on the size of "target lesions"
- Suggestions for optimization
- Response assessment methodology
- Incorporation of Clinical Oncology Reviews

Robert R. Ford, M.D., Chief Medical Officer and Co-Founder, RadPharm

12:30 *Luncheon*

Hosted by:



1:45 **Imaging Provides Useful Investigational Endpoint — Millennium Pharmaceuticals' New Cancer Therapeutic, Velcade**

Hear how imaging was used as an investigational endpoint of tumor response in the clinical trial of a new cancer therapeutic, Velcade, used for the treatment of multiple myeloma.

- Imaging technology utilized in the clinical trial of Velcade
- Pharmacogenomics — Phase II and III of Oncology Clinical Trials
- The role of transcriptional profiling to identify disease pathways

Gerry Linette, M.D., Ph.D., Director of Molecular Medicine, Millennium Pharmaceuticals

**DAY TWO KEYNOTE ADDRESS**

2:30 **Clinical Applications of the International Working Group Response Criteria for Non-Hodgkin's Lymphoma — Operationalize the "Cheson" Criteria**

Commonly referred to as the "Cheson" criteria, named after its first author, the International Working Group Response Criteria (IWRC) for Non-Hodgkin's Lymphoma (NHL) was published in 1999. The IWRC is now the standard criteria for response evaluation in NHL, and was successfully applied to the rituximab studies. Hear firsthand from the initiator of the IWRC effort, one of the original authors of the criteria, how to strategically apply this response criterion to clinical trials.

- How does this criteria apply?
- What is the best technique to use when evaluating response in NHL?
- Can we predict the complexities in the criteria, and how can they be overcome?

Antonio J. Grillo-Lopez, M.D., Chair, **Neoplastic and Autoimmune Disorders Research Institute**; Former Chief Medical Officer and Senior Vice President, Medical and Regulatory Affairs, **IDEC Pharmaceuticals**

Dr. Grillo-López is currently the Chairman, Neoplastic and Autoimmune Diseases Research Institute. Between 1980 and 1987, he was Vice President, Clinical Therapeutics and Director, Clinical Oncology Research at Warner Lambert Company's **Parke Davis** Pharmaceutical Research Division. Dr. Grillo-López spent 5 years at **DuPont Merck** Pharmaceuticals, where he was Executive Medical Director for International Clinical Research and Development. He joined IDEC Pharmaceuticals in November 1992 where he was Chief Medical Officer and Senior Vice President, Medical and Regulatory Affairs. He was the project clinician in the development of Rituxan (the first monoclonal antibody for the treatment of cancer) and supervised the development of Zevalin (the first radiolabeled antibody for the treatment of cancer). He co-authored the current international response criteria for lymphoma.

3:15 *Close of Conference*

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CBI'S WEST COAST FORUM ON

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Antonio J. Grillo-Lopez, MD, Chair, **Neoplastic and Autoimmune Disorders Research Institute**; Former Chief Medical Officer and Senior Vice President, Medical and Regulatory Affairs, **Idec Pharmaceuticals**

## EXPERTS FROM THESE LEADING COMPANIES AND INSTITUTIONS:

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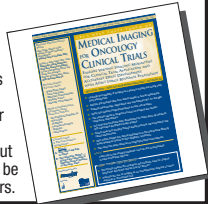
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## PLUS! CHOOSE FROM 2 MORNING WORKSHOPS:

- A. A Primer — Why, When and How to Image
- B. Operationalize RECIST — Incorporate Independent Endpoint Review Charters in Oncology Trials

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