February 12–13, 2018 | The Argonaut | San Francisco, CA

MEDICAL IMAGING IN CLINICAL RESEARCH

Implementing the Newest Technology to Optimize Imaging Data in Clinical Research

KEY THEMES

- **CLINICAL TRIALS**
- **MANAGING DATA**
- **STANDARDIZATION**
- **ADOPTING TECHNOLOGY**

CHAIRPERSON

Colin Miller
Editor
MEDICAL IMAGING IN CLINICAL TRIALS

FEATURED SPEAKERS

Neeta Fahey
Clinical Imaging Operations/Clinical Project Manager Professional
BRISTOL-MYERS SQUIBB

Priya Guyadeen
Clinical Project Manager, Peripheral
PENUMBRA, INC.

Debbie N. Coté, RN
Director, Clinical Operations
NEKTAR THERAPEUTICS

Youngho Seo, Ph.D.,
Professor, Department of Radiology and Biomedical Imaging
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

Dr. Johan Luthman
Vice President Neuroscience Clinical Development
EISAI

Ira Smalberg, M.D.,
Diagnostic Radiology,
TOWER IMAGING MEDICAL GROUP

Shawn Keen
Associate Director, Imaging Partner Relationship Lead
BRISTOL-MYERS SQUIBB

Gary Ulaner, M.D., Ph.D.,
Associate Attending Radiologist, **MEMORIAL SLOAN KETTERING CANCER CENTER**

WHO SHOULD ATTEND

This event is designed for professionals from the pharmaceutical, biotechnology, and medical device companies with responsibilities or involvement in the following areas:

- Clinical Imaging
- Clinical Operations
- Clinical Research
- Clinical Development
- Clinical Data Management
- Therapeutic Area Heads
- Data Management
- QA/QC
- Biometrics
- Protocol Management
- Translational Biomarkers

The conference will also benefit any imaging consultants, CROs, technology vendors, and companies providing services to the above audience.

Dear Colleague,

ExL Events' **Medical Imaging in Clinical Research** conference brings together senior-level executives from academia, pharmaceutical, biotechnology, and medical device companies to examine the roles of various imaging modalities in clinical research. There are significant benefits to using imaging during clinical trials, which this forum will address in order to help improve the quality of these trials. Imaging in early phases can be used as a biomarker to validate a hypothesis or to make Go/No-Go Decisions to further drug development. During late phases, imaging data can contribute to the potential of expediting the Health Authority approval process. However, with first-time implementation of imaging technology, challenges arise. The main challenge facing clinical operation teams during clinical research is the harmonization and standardization of imaging processes and data collection.

Join us for thought-provoking, interactive sessions to ensure you have all your questions answered. Gain key insights behind the implementation of various imaging modalities during clinical research, and the challenges and opportunities of using each. You will leave the Medical Imaging in Clinical Research conference prepared to implement the newest technology to optimize imaging data in clinical research.

I look forward to welcoming you to San Francisco in February!

Sincerely,

Christopher Summa

Christopher Summa
Conference Production Director
ExL Events

VENUE

The Argonaut | 495 Jefferson Street | San Francisco, CA 94109

To make reservations, guests can call **877-662-5387** and request the rate for **ExL's February Meetings**. You may also make reservations online at http://bit.ly/2gWl5Oe. The conference room rate is $239 + tax per night. Reservation cut-off date is **January 22, 2018**.

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8:30 Continental Breakfast and Registration

9:30 **Chairperson's Opening Remarks — Advanced Methods for Read Designs and Inter-Reader Variability**

- Identify the appropriate metrics to improve imaging studies
- For large studies, how to manage a large reader pool
- Latest publications on and inter–intra-reader variability
- Update on PINTAD paper on inter-reader availability

Colin Miller, *Editor,* **MEDICAL IMAGING IN CLINICAL TRIALS**

10:00 **Strategically Plan and Manage Imaging in Your Clinical Trial to Ensure Standardization Across Vendors**

- Choose the right vendors/partners that are equipped to handle your needs
- Train and select site teams to ensure protocol is uniform
- Ensure the proper protocol and procedures are in place to meet regulatory guidelines

Neeta Fahey, *Clinical Imaging Operations, Senior Clinical Protocol Manager,* **BRISTOL-MYERS SQUIBB**

11:00 Networking Break

11:30 **Implement PET Imaging As a Potential Go/No-Go Decision in Early-Phase Clinical Trials**

- Proper study design to assess target/off-target exposure
- Create the curve between the rate of target engagement versus different doses of the drug
- Understand the difference in PET imaging application for drug development versus diagnostic purposes

Jianqing Chen, *PET and Molecular Imaging,* **PFIZER**

12:30 Luncheon

1:45 **Incorporate Experimental Imaging Agents in Drug Clinical Trials**

- Utilize PET and SPECT imaging agents as biomarkers in clinical trials
- Implement kinetic modeling and other innovative image processing as a primary study endpoint
- Use hybrid imaging modalities to provide a complete picture of patients' health
- Molecular imaging approaches for drug development to determine drug toxicity and efficacy in animal trials

Youngho Seo, Ph.D., *Professor, Department of Radiology and Biomedical Imaging,* **UNIVERSITY OF CALIFORNIA, SAN FRANCISCO**

Gary Ulaner, M.D., Ph.D., *Associate Attending Radiologist,* **MEMORIAL SLOAN KETTERING CANCER CENTER**

2:45 **Adopt Electronic Transfer of Imaging Data Across the Industry**

- Improve speed of imaging results transferred from site to sponsor
- Integrate electronic transfer across multiple platforms to promote standardization and develop better processes
- Implement standard operating procedures across all sites to ensure changes remain effective

Shawn Keen, *Associate Director, Imaging Partner Relationship Lead,* **BRISTOL-MYERS SQUIBB**

3:45 **Operationalize Imaging Management in Clinical Research Trials**

- Oversee global trials that utilize imaging technologies
- Optimize operational and trial workflow through standardized and best practices
- Manage site imaging requirements: Ensure staff is properly trained and prepared for all situations

Debbie N. Coté, RN, *Director, Clinical Operations,* **NEKTAR THERAPEUTICS**

4:45 **Track Lesions Over Time Using MRI and CT Modalities**

- Bridge the gap between technology and medicine to improve patient outcomes
- Observe tumor growth with noninvasive monitoring approaches
- Implement artificial intelligence and machine learning to improve healthcare delivery

5:45 Conference Day One Ends

"Accelerated approval allows a drug to reach the market based on what are called intermediate or surrogate clinical trial endpoints — measures like imaging data or markers in blood that are predictive of longer-term disease outcomes like survival. Compared with the standard approval pathway, that can mean fewer, shorter, or smaller trials."

—SCIENCEMAG.ORG

8:00 Continental Breakfast

9:00 **Chairperson's Recap of Day One — Imaging Differences Between Efficacy, Safety and Eligibility Reads for Phase Two and Phase Three Studies**

- Single– and two-reader paradigms — which one to use?
- Ethical considerations for eligibility reads
- Study setup considerations

Colin Miller, *Editor,* **MEDICAL IMAGING IN CLINICAL TRIALS**

9:30 **Combat and Prepare for the Additional Costs Associated With Imaging Modalities**

- Staff costs: Project manager, medical imaging technologist, biostatistician, radiologist, technical services manager, imaging scientist or physicist, and a clinical IT/software specialist
- Identify the break-even point when implementing advanced software systems
- Manage and budget for new logistics: Site setup, management, and image data transfer

10:30 **Reader Challenges in Central Independent Reviews**

- Balance clinical work with primary work responsibilities
- Handle technical issues: Transfer of data, poor internet connections, tight turnaround time
- Adjust to various systems and procedures at multiple core labs

Ira Smalberg, M.D., *Diagnostic Radiology,* **TOWER IMAGING MEDICAL GROUP**

11:30 Networking Break

12:00 **Treatment of Neurological Disorders Using Molecular Imaging As a Guide**

- Evaluate CNS disorders in animal and experimental human models
- Importance of the imaging agent during a molecular study
- Identify the best modalities to use during a molecular imaging study

Dr. Johan Luthman, *VP Neuroscience Clinical Development,* **EISAI**

1:00 Luncheon

2:15 **Utilize Imaging Modalities for Randomization and Endpoint Adjudication**

- Implement strategic partnerships: How to choose the right vendors
- Understand your study design to see how imaging fits
- Manage your vendors to adhere to your timelines

Priya Guyadeen, *Clinical Project Manager, Peripheral,* **PENUMBRA, INC.**

3:15 **Ultrasound in Place of CT for the Benefit of the End Users**

- Examine the key differences between ultrasound and other major imaging modalities
- Improve patient care through less intrusive procedures by eliminating radiation, while being able to report results in real time
- Implement procedures to train professionals to accurately read ultrasounds

4:15 **Chairperson's Closing Remarks**

Colin Miller, *Editor,* **MEDICAL IMAGING IN CLINICAL TRIALS**

4:30 Conference Concludes

Testimonials From Past ExL Events

"Great information was shared followed by dynamic discussions!"

—Senior Director, Data Management, **DAIICHI SANKYO**

"Great presentations, topics and conversation."

—Clinical Planning and Analysis Specialist, **ACORDA THERAPEUTICS**

"Relaxed format with open discussions yielding different points of view."

—Director of Global CQA, **TEVA**

"Excellent examples, engaging presentations. Really enjoyed the overall experience!"

—Senior Manager, Process Improvement, Developmental Sciences, **BIOMARIN PHARMACEUTICALS**

"Very thought-provoking and shows good direction in the industry."

—Senior Manager of Outsourcing, **ASTELLAS**

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EARLY BIRD PRICING *Register by Friday, December 22, 2017*	**$1,895**
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MEMORIAL SLOAN KETTERING CANCER CENTER

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