




B1 Overcome Outsourcing & Operational Challenges for Smaller Companies

• Monday January 26, 2009 • Red Rock Casino & Spa

Located in Charleston DE

8:00	Registration and Morning Coffee hosted by 
9:00	Best Practices in Outsourcing to Central Labs to Improve Efficiencies Gary Albert, Manager Clinical Operations, ALNYLAM PHARMACEUTICALS
10:00	Building the Checklists-Qualification, Selection, and Operating Tools to Save You Time Donna Saligan, MBA, MT (ASCP), Contracts and Outsourcing Manager, RH BOUCHARD ASSOCIATES
10:30	Morning Networking Break in Red Rock Foyer
11:00	Building the Checklists-Qualification, Selection, and Operating Tools to Save You Time Donna Saligan, MBA, MT (ASCP), Contracts and Outsourcing Manager, RH BOUCHARD ASSOCIATES
11:45	Going Global: Strategies for Success Guy Dewil, PhD, Chief Operating Officer, ICON CENTRAL LABORATORIES
12:30	Networking Luncheon in Pavilion Ballroom
1:30	Navigating ECG RFPs and Maximizing the Continuum of Service Kristian B. Hubbard, Manager, Outsourcing, EISAI MEDICAL RESEARCH
2:30	How Continuous Improvement and Targeted Metrics Yield Dramatic Gains for Sponsors And Imaging Core Labs Jeff Markin, President and CEO, VIRTUALSCOPICS Annette Chan, PhD, Manager-Medical Imaging Technical Services, AMGEN
3:15	Afternoon Networking Break in Red Rock Foyer
3:45	How to Reduce the Burden on Smaller Sponsor Clinical Team-The Cross Functional Approach Moderator: Solomon Babani, Director, Celtic Pharma, DEVELOPMENT SERVICES Panelists: Karen H. Turner, Senior Contract Analyst Global Resourcing, Grants & Contracts (GRGC), GLAXOSMITHKLINE Arnold Verbeek, Managing Director, Clinical trials, CRL, CLINICAL REFERENCE LABORATORY Rhonda Benotti, Development Outsourcing & Contracts, GENENTECH Chris Helton, MT(ASCP), MBA, Director of Data Management and Clinical Systems, ACM PIVOTAL
4:30	Working with a Central Laboratory to Help Control your Clinical Trial Costs Panelists: Marietta M. Henry, MD, Vice President, Medical Affairs and Global Laboratory Medical Director, COVANCE CENTRAL LABORATORY SERVICES Susan Martin, MD, Director, Medical Affairs, COVANCE CENTRAL LABORATORY SERVICES Maria Taboada, Associate Director, Global Logistics, COVANCE CENTRAL LABORATORY SERVICES Millie Marsh, Global Director, Site Support, COVANCE CENTRAL LABORATORY SERVICES
5:15	Networking Reception Sponsored by HUNTINGDON LIFE SCIENCES in Veranda Room



B2 Getting the Most Technical Expertise from Your Labs: Biomarkers, Personalized Medicine, Diagnostics, and Assay Development


● Monday January 26, 2009 ● Red Rock Casino & Spa
Located in Charleston AF




8:00	<i>Registration and Morning Coffee hosted by</i>  WORLD COURIER <small>A SERVICE NO ONE ELSE CAN DELIVER</small>
9:00	Personalized Medicine and Its Impact on Drug development and Commercialization David Lester, Senior Vice President, Strategy and Corporate Development, GENE EXPRESS
9:30	Companion Diagnostics: Implementation models for Rx/Dx Co development Concept David Johnston, PhD, Vice President, Companion Diagnostics, LABCORP ; Chief Scientific Officer, ESOTERIX CLINICAL TRIALS SERVICES
10:00	Biomarkers in Oncology Greg Bannish, Associate Director, Experimental Biology, HUNTINGDON LIFE SCIENCES
10:30	<i>Morning Networking Break in Red Rock Foyer</i>
11:00	Biomarkers as Potential Companion Diagnostics: A New Paradigm for Central Laboratories Services Maribeth Raines, PhD, Director, Scientific Affairs, QUEST DIAGNOSTICS CLINICAL TRIALS
11:30	Archival Surgical Pathology Specimens: A New Exercise in Clinical Trials Carol W Johnson, DVM, PhD, DACVP, Pathology Director, AMGEN - Invited Joseph Schappert, MD, Global Medical Director, ICON CENTRAL LABORATORIES
12:00	Bridging the Gaps in Biomarker Development and Testing for Global Clinical Trials Biomarkers, Digital Pathology & the Central Lab Christopher Ung, M.S., MBA, Vice President, Clinical Lab, TMD, A QUINTLES CENTRAL LABORATIES
12:30	<i>Networking Luncheon in Pavilion Ballroom</i>
1:15	Case Studies using Biomarkers for Dosage in Phase I, Early Detection of Nephrotoxicity and Diagnosis of Schizophrenia: The Rules-Based Medicine Approach. Ralph McDade, PhD, Strategic Development Officer, RULES BASED MEDICINE
1:45	The Use of Imaging Biomarkers in Phase I/II trials Haren Rupani, Global Head, Oncology Clinical Imaging, NOVARTIS PHARMACEUTICALS CORPORATION
2:15	Using Technical Consulting Services to Avoid Pitfalls in Biomarker Data Collection Rajani Prasad, M.D, FACR, FACNP Global Head, Oncology Clinical Imaging, CRL CLINICAL REFERENCE LABORATORY
2:45	Using Robust QT in Drug Development for Earlier Evaluation and Compound Advancement William Wheeler, MD, FACC, Global Medical Director, Centralized Cardiac Services, MDS PHARMA SERVICES
3:15	<i>Afternoon Networking Break in Red Rock Foyer</i>
3:45	Kidney Injury Molecule-1: Biology and Analytical Validation Tom Turi, VP Biomarkers, COVANCE CENTRAL LABORATORY SERVICES
4:30	Technical Hot Topics Panelists: Haren Rupani, Global Head, Oncology Clinical Imaging, NOVARTIS PHARMACEUTICALS CORPORATION David Lester, Senior Vice President, Strategy and Corporate Development, GENE EXPRESS David Johnston, PhD, Vice President, Companion Diagnostics, LABCORP ; Chief Scientific Officer, ESOTERIX CLINICAL TRIALS SERVICES Ralph McDade, PhD, Strategic Development Officer, RULES BASED MEDICINE
5:15	<i>Networking Reception SPONSORED BY HUNTINGDON LIFE SCIENCES in Veranda Room</i>




**Centrals Labs, EGG & Imaging Labs • January 27-28, 2009 • Red Rock Casino & Spa
General Session Located in Charleston Ballroom**

Tuesday January 27th, 2009

7:30	Registration and Morning Coffee hosted by 		
8:15	Chairperson's Welcome Robert Scott-Edwards, President, ICON CENTRAL LABORATORIES Cynthia Lindemann, Associate CDS Consultant/Central Laboratory Coordinator, Clinical Diagnostic Services, ELI LILLY & COMPANY		
8:30	Featured Session: The Changing Face of R&D: Trends in New Drug Development Kenneth I. Kaitin, PhD, Director and Professor of Medicine, TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT		
9:30	Drug Safety Evaluation: Benefit-Risk Assessments throughout Development and Therapy J. Rick Turner, PhD, President and Chief Scientific Officer, TURNER MEDICAL COMMUNICATIONS LLC		
10:15	Networking Break in Red Rock Foyer		
11:00	Improve Operational Success by Developing Vendor Quality Management Plans Marie Ulrich Gallo, Vendor Quality Manager, GLOBAL VENDOR QUALITY MANAGEMENT a division of Global Clinical Trial Logistics, WYETH RESEARCH Arnold Verbeek, Managing Director, Clinical Trials, CRL, CLINICAL REFERENCE LABORATORY		
11:45	Current and Future Metrics Champion Consortium Metrics Initiatives Guy Mascaro, President, Metrics Champion Consortium, MCC David Rauh, Clinical Diagnostic Services Imaging Management, ELI LILLY & COMPANY Sue Hwang, Senior Manager, R&D Global Strategic Sourcing, AMGEN Steve Asbury, Global ECG Coordinator, ELI LILLY & COMPANY		
12:15	Strolling Networking Luncheon in Exhibit Hall		
	Track A: Central Lab Relationship Development (Charleston Ballroom)	Track B: Standardization in Imaging Studies (Veranda DE)	Track C: Improving & Standardizing ECG & Cardiac Safety Studies (Veranda C)
1:30	Chairperson's Opening Remarks Clare O'Sullivan, General Manager, ICON Central Laboratories, Dublin	Chairperson's Opening Remarks David Rauh, Clinical Diagnostic Services Imaging Management, ELI LILLY & COMPANY	Chairperson's Opening Remarks Tim Callahan, PhD, Chief Scientific Officer, BIOMEDICAL SYSTEMS
1:35	Improve Patient Care, Transparency and Process Efficiency in Global Studies Solomon Babani, Director, CELTIC PHARMA DEVELOPMENT SERVICES Scott Sawicki, MA, Section Head, Central Laboratory & Diagnostic Services, CRO Management, NOVARTIS PHARMACEUTICALS CORPORATION Stephanie Talbott, Vice President, Global Business Development, ICON CENTRAL LABORATORIES Heidi Egelhoff, Manager, Business Development, UBC CLINICAL TECHNOLOGIES GROUP	Current Standardization Initiatives for Use of Imaging in Clinical Trials P David Mozley, MD, Senior Director, MERCK & COMPANY	Update on FDA Guidance for ECG Related Studies Jeffrey Litwin, MD, Chief Medical Officer & Executive Vice President, eRESEARCHTECHNOLOGY
2:00	Central Lab Cost Drivers and Logistics Discussion Forum John Monetti, Vice President, Sales and Marketing, WORLD COURIER Scott Sawicki, MA, Section Head, Central	MCC METRICS: Metrics Champion Consortium Imaging Performance Metrics Announcement David Rauh, Clinical Diagnostic Services	ECG Data Integration and Standardization with CDM/ EDC Systems

	Laboratory & Diagnostic Services, CRO Management, NOVARTIS PHARMACEUTICALS CORPORATION Rajani Prasad, PhD, Vice President of Clinical Trials, Clinical Research, CRL, CLINICAL REFERENCE LABORATORY Mike Harvey, Managing Director of Operations, QUEST DIAGNOSTICS	Imaging Management, ELI LILLY & COMPANY	Jane Gale, Principal, Gale-Bentz Consulting
	Track A: Central Lab Relationship Development (Charleston Ballroom)	Track B: Standardization in Imaging Studies (Veranda DE)	Track C: Improving & Standardizing ECG & Cardiac Safety Studies (Veranda C)
2:30	Support of Local Laboratories by a Central Laboratory in Global Phase III Oncology Trials Jaap H.M. Dijkman, MD, MBA, PPM, Senior Director, Business Development, COVANCE CENTRAL LABORATORY SERVICES Dr. Marc-Ulrich Häusler, Senior Clinical Data Manager, Global Data Management, MERCK SERONO DEVELOPMENT/ GLOBAL CLINICAL OPERATIONS	Utility of Imaging in Clinical Trials- Strategies for Success Craig Lipset, Director, Molecular Medicine, PFIZER	New Equipment and Software Technology Landscape Moderator: Tim Callahan, PhD, Chief Scientific Officer, BIOMEDICAL SYSTEMS Panelists: Dr. Tosja K. Zywiets, Chief Scientist CARDINAL HEALTH RESEARCH SERVICES
3:00	<i>Networking Break in Exhibit Hall Hosted by:</i>  mes <small>Medical Imaging & Software Solutions</small>		
3:45	Best Practices for Collecting and Integrating Data in International Clinical Trials Jennifer Duff, Associate Director, ACCENTURE AT WYETH Greg Burgess, Manager, External Data Acquisition Operations, SPRI	Bridging Small Imaging Studies to Large Imaging Studies for Smoother Transitions James Paskavitz, MD, Medical Director, PERCEPTIVE INFORMATICS Donald Cooper, Director Project Management, BIOMEDICAL SYSTEMS George Mills, PhD, Vice President, Medical Imaging Consulting, PERCEPTIVE INFORMATICS	Methods to Mitigate the Potentially Distorting Effect of Heart Rate in QT Analyses Polina Voloshko, Vice President, Medical Operations, CARDIOCORE
4:15	Risk Management for Global Studies Beth Sabatino, Outsourcing Manager, BRISTOL-MYERS SQUIBB	Standardizing Intra/Inter Observer Variability and Adjudication Rates in Imaging Studies David L. Raunig, PhD, Associate Director, Imaging Translational Technologies Statistics, Pfizer Global Research and Development Jim Conklin, MD, Senior Vice President, ICON MEDICAL IMAGING Ed Ashton, Chief Scientific Officer, VIRTUAL SCOPICS	Using the MCC ECG Metrics Jeffrey Litwin, MD, Chief Medical Officer & Executive Vice President, eRESEARCHTECHNOLOGY Steve Asbury, Global ECG Coordinator, ELI LILLY & COMPANY
4:45	Development of Central Laboratory in China- Challenges and Opportunities James J Ho, MD, PhD, DABCC, Chief Executive Officer/ Lab Director, PEKING UNION LAWKE BIOMEDICAL DEVELOPMENT LIMITED		Hot Topics and Trends in Cardiac Safety Studies Moderator: Tim Callahan, PhD, Chief Scientific Officer, BIOMEDICAL SYSTEMS Panelists: Jay Mason M.D., Cardiac Safety Consultant, OBS MEDICAL
5:15	<i>Tuesday Concludes/ Reception in Exhibit Hall Hosted by:</i>  ESOTERIX <small>ESOTERIX Clinical Trial Services</small> <i>A LabCorp Company</i> located in the Veranda Room		
Wednesday January 28th, 2009			
8:15	<i>Morning Coffee Hosted by:</i>  WORLD COURIER <small>A SERVICE NO ONE ELSE CAN DELIVER</small>		
9:00	Chairperson's Recap of Day One		

	<p>Robert Scott-Edwards, President, ICON CENTRAL LABORATORIES Cynthia Lindemann, Associate CDS Consultant/Central Laboratory Coordinator, Clinical Diagnostic Services, ELI LILLY & COMPANY</p>		
9:15	<p>Strengthening the Sponsor / Vendor / Site Relationship. What Do Sites Really Think? Site Survey- Sites' Perspective to Improve Efficiency and Quality in Clinical Trials Gary Albert, Manager Clinical Operations, ALNYLAM PHARMACEUTICALS William Smith, President, Clinical Research, NEW ORLEANS CENTER FOR CLINICAL RESEARCH Clare O'Sullivan, General Manager, ICON CENTRAL LABORATORIES, Dublin</p>		
10:00	<p>Incredible Change: Overcome your Partnering Obstacles with the "Hulk" Lou Ferrigno, "THE INCREDIBLE HULK"</p>		
10:45	<p>Networking Break Visit MDS Pharma Services at booth 402 to meet Lou Ferrigno</p> 		
11:30	<p>Sample Management: Tracking Global Lab Samples to Ensure you Get the Data Adam Ruskin, President, FocusMonitoring.com</p>		
12:00	<p>Comparing Approaches: Preferred Providers vs Competitive Bidding, What is your Best Choice? Panelists: Diane Stinson, External Services Group, MERCK & COMPANY Jim Meringolo, Vice President of Finance and Administration, ICON CENTRAL LABORATORIES Roberto Vaccaro, Senior Manager, Electronic Data Services R&D Strategic Sourcing & Procurement, AMGEN</p>		
12:30	<p><i>Networking Luncheon in Exhibit Hall</i></p>		
	<p>Track A: Central Lab Relationship Development\ (Charleston Ballroom)</p>	<p>Track B: Standardization in Imaging Studies (Veranda DE)</p>	<p>Track C: Improving & Standardizing ECG & Cardiac Safety Studies (Veranda C)</p>
1:30	<p>Chairperson's Opening Remarks Stephanie Talbott, Vice President, Global Business Development, ICON CENTRAL LABORATORIES</p>	<p>Chairperson's Opening Remarks David Rauh, Clinical Diagnostic Services Imaging Management, ELI LILLY & COMPANY</p>	<p>Chairperson's Opening Remarks William Wheeler, MD, FACC, Global Medical Director, Centralized Cardiac Services, MDS PHARMA SERVICES</p>
1:35	<p>Overview of Metrics: Definition Refinement & Update from the Central Lab MCC Initiative Sue Hwang, Senior Manager, R&D Global Strategic Sourcing, AMGEN Cynthia Lindemann, CDS Consultant, Central Laboratory ,Coordinator, Clinical Diagnostic Services, ELI LILLY & COMPANY Alissa Kerry, Sr. Manager, Business Process Measurements COVANCE CENTRAL LABORATORY</p>	<p>Charter Development and Industry Standardization with FDA/ PhRMA Derek Hill PhD, Co-founder and CEO, IXICO</p>	<p>Working Together to Develop Biomarkers for Safety Monitoring and Surrogate Endpoints Samir Khleif, Head, Cancer Vaccine Section Investigator, NATIONAL CANCER INSTITUTE, NIH Wendy R. Sanhai, PhD, Senior Scientific Advisor, Office of the Commissioner, FDA William Wheeler, MD, FACC, Global Medical Director, Centralized Cardiac Services, MDS PHARMA SERVICES</p>
2:15	<p>Panel Discussion Reducing Costs at Investigator Sites through Process Improvement Jennifer Christie, Master Black Belt, COVANCE CENTRAL LABORATORY SERVICES Jonathan Koch, Vice President, Global Clinical Trial Management & Operations, COVANCE CENTRAL LABORATORY SERVICES Joan Banos, CPSM, C.P.M., CPIM, PMP, Green Belt Senior Sourcing Manager, Central Laboratories, JOHNSON & JOHNSON</p>	<p>Building the Imaging Lexicon for Rate Cards to Improve Industry Consistency P. David Mozley, MD, Senior Director, MERCK & COMPANY</p>	<p>Patrice Hugo, Vice-President of Scientific Affairs, MDS PHARMA SERVICES</p>
3:00	<p><i>Conference Concludes</i></p>		