7th Annual Conference

Discovery through Commercialization:

Innovative Strategies for Individualized Health Care

November 1-4, 2012

ID #12659 | Hyderabad International Convention Center

PROGRAM ADVISOR

Narges Mahaluxmivala
Senior Consultant
Clinical Development Research

CHAIR, ADVISORY COUNCIL OF INDIA

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VP Global Functional Resourcing, Asia
Quintiles, Singapore

PROGRAM COMMITTEE

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US FDA, India

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President
Global Alliance of Indian Biomedical Professionals
USA

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Vice President and Country Manager, India
PAREXEL International

V. N. Balaji
Consultant, Discovery Research

Nikhil Kumar
President
Applied Technology Solutions, Inc, USA

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Scientific Director
Duke Global Proof-of-Concept Research Network
Duke Clinical Research Unit &
Duke Clinical Research Institute, USA

Carol Isaacson Barash
Principal, Helix Health Advisors
Adjunct Prof. Personalized Medicine, Regis College

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Interlink Marketing Consulting, India

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Equnev Capital

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Senior Director, Regulatory Medical Writing
Janssen R&D Companies of J&J, USA

Uday Kumar S
Head – Project & Alliance Management
Rhizen Pharmaceuticals S A, Switzerland

SCIENTIFIC ADVISOR - POSTERS

N. Udupa
Professor and Principal
College of Pharmaceutical Sciences, Manipal, India

An excellent opportunity to showcase your products and services through exhibits and advertisements.

KEYNOTE SPEAKERS

Paul Huckle
Senior Vice President,
Global Regulatory Affairs
GlaxoSmithKline

Adrian McKemey
Practice Leader, Product Development
& Commercialization
Quintiles

PROGRAM CO-CHAIRS

Nimita Limaye, PhD
Vice President
Biometrics & Medical Writing
Tata Consultancy Services

Vishwanath Iyer, PhD
Head, Oncology Biometrics
Novartis Healthcare

Over a period of time, there has been a paradigm shift in the way medicines are being developed. Therapy is becoming patient-centric and technology is driving real-time monitoring of patient responsiveness. This necessitates changes in the way every aspect of the health care industry, from discovery through development, manufacturing, and finally commercialization operate.

This conference will include multiple tracks focusing upon the confluence of discovery, development, manufacturing and commercialization towards the development of innovative, path-breaking strategies in the realm of personalised health care. The conference will address the strategy for drug discovery and clinical development pipeline and faster time to market in the era of blockbuster patent expiries and issues of integrating and streamlining data flows across the entire life cycle of the molecule, and the standardization and rigor that needs to be implemented. It will also stress upon the ethical, legal, social and regulatory and financial and investment challenges impacting all of the above and how processes and technology will need to be upgraded to support the same.

PROGRAM HIGHLIGHTS

- Discovery: Bioinformatics, Next Gen Sequencing, Lead optimization – the need for speed
- Development: Barriers and drivers relevant to clinical development across clinical operations, data management, biostatistics, programing, and medical writing, highlighting systems biology paradigm (e.g. pharmacogenomics, metabolomics) and innovative developmental approaches (e.g. chronotherapeutics, microdosing)
- Manufacturing: Flexible solutions to adapt to the evolving global regulatory scenario and quality standards
- Commercialization: Health economics and outcomes research driving product and pricing strategy, patient access, payor challenges, Go-to-investors and financial/partnering strategies for product development
- Regulatory, ethical, social and legal issues: data privacy and consent issues in the evolving technologies related to personalized medicine
- Technology and Standards: Technology – SOA, the Cloud and the future, Data and Semantic Interoperability Technology, GRC (Governance, Regulation and Compliance) all focused on Personalized Medicine.
- Lean strategy: The application of Lean in pharmacovigilance, medical writing, clinical operations and site performance. Driving the critical path.

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Andheri (East), Mumbai - 400059

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9.00-12.00AM

QbD: A Challenge to the Pharma Industry (MR 1.01)

INSTRUCTORS

V. Venkateswarlu
Vice President, Functional Head of Formulation Development, Bioequivalence and Clinical Pharmacokinetics
Packaging Development - Integrated Product Development,
Dr. Reddy's Laboratories

R. Manikandan
Associate Director, Formulation Development
Dr. Reddy's Laboratories

Quality by Design is defined as a systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management. The important stakeholders involved in this process are patients, industry and regulators. For patients, it is quality, efficacy and safety, for industry, it is important to have quality along with cost saving and efficiency and for regulators, it is more efficient regulatory oversight. Integrating these aspects is a question to industry and regulator and hence it is a challenge to the pharma world. The reason for calling it as a challenge because the twenty-first century began with the pharmaceutical industry using development approach (empirical) and manufacturing technologies that have been employed since the 1940's. No significant changes in manufacturing process is made until it justifies the high costs and long cycle time needed to gain approval. This often resulted in inefficient, overly expensive processes. As a result, the FDA have embrace a new paradigm for regulation through Quality by Design.

The FDA belief is that, quality cannot be tested into products, but should be built-in or by design. The important elements that will enable to institutionalize this includes, quality target product profile, critical quality attribute, design space, risk assessment, control strategy and continuous improvement. The detail approach towards application of these elements is also well enumerated in ICH guidelines Q8, Q9, Q10 and Q11. Therefore, Implementation of QbD will enable transformation of the chemistry, manufacturing, and controls (CMC) review of new drug applications (NDA's) and Abbreviated new drug applications (ANDAs) into a science-based pharmaceutical quality assessment

As Janet Woodcock, Officer at FDA, stated at the 2008 PDA meeting, *'QbD is an evolution and not a revolution'* – an evolution that is in response to the increasing cost pressures on both the regulatory agencies and industry. QbD will evolve as we continue to increase our understanding and control of the manufacturing processes.

Learning Objectives:

- Emphasis on the importance of the Quality Target Product Profile in articulating a quantitative performance target for QbD
- Identification of critical material attributes that provide a mechanistic link of the product quality to the manufacturing process
- Critical process parameters are operating parameters and should be combined with critical material attributes to describe the relation between unit operation inputs and outputs
- Establishing the design space and enable the changes within design space
- The role of the control strategy as the mechanism for implementation of QbD elements into practice
- Life cycle management – propose post approval changes needed through continuous improvement

2.00-5.00PM

Bioinformatics (MR 1.01)

INSTRUCTOR

Sangeeta Sawant
Assistant Professor (Reader),
Bioinformatics Center, University of Pune

Bioinformatics has evolved as a multidisciplinary area of science over the past few decades. It has become an integral component of research and education in life sciences. Having originated as a set of computational tools to analyze biological data such as biomolecular sequences and structures, Bioinformatics now deals with computational processing and analysis of large sets of complex data being churned out from advanced and high throughput technologies such as DNA micro-arrays, whole genome sequences, proteomics data, protein-protein interactions etc. A large variety of mathematical algorithms and statistical techniques are employed for data analysis.

Bioinformatics facilitate simple sequence-based or structure-based analyses of genes and proteins to gain insights into their molecular functions on one hand and provide insights into systems level biology through analysis of voluminous genomic or proteomic data. The paradigm shift from molecular level studies in life sciences to systems biology, genotype-phenotype correlations, insights into health and disease states, etc. is being greatly accelerated by bioinformatics applications.

Learning Objectives:

- To understand the scope of Bioinformatics and introduce sequence-based approaches: What can be achieved by using the sequence analysis methods
- To introduce structure-based approaches: What can be achieved by analyzing structures of biomolecules
- An overview of applications of bioinformatics-based methods in various life science areas such as drug design, genetics and genetic diseases, infectious and parasitic diseases, immunology, etc.

2.00-5.00PM

Personalized Medicine (Organiser's Suite)

INSTRUCTORS

Carol Isaacson Barash
Principal, Helix Health Advisors
Adjunct Prof. Personalized Medicine, Regis College

Jeffrey N Gibbs
Director
Hyman, Phelps & McNamara P.C.

It is an introduction to the field of personalized medicine and how and why it is revolutionizing the practice of medicine. Topics include pharmacogenetics/pharmacogenomics, molecular diagnostics used to tailor therapies, companion diagnostics and strategies for revitalizing older drugs. An overview of current and emerging technologies used, therapeutic domains and regulatory challenges and ethical issues will be discussed.

Attendees will:

- Understand the FDA regulatory system for *in vitro* diagnostics, and what that means for the drug approval process
- Learn how to work collaboratively with *in vitro* diagnostic companies during the clinical trial and the application process to obtain approval of drug and the companion diagnostic
- Learn how to structure contracts with an *in vitro* diagnostic company developing a companion diagnostic for your drug
- Learn about the pitfalls on the path to getting approval of the companion diagnostic for your drug
- Learn about FDA regulation of laboratory developed tests (LDTs) and the role of LDTs in companion diagnostics
- Learn stakeholder interests and concerns
- Learn ethical issues in clinical trials and informed consent
- Learn privacy issues in data collection, storage, use and disclosure

8.15-9.00 AM REGISTRATION

9.00-9.15 AM OPENING CEREMONY (HALL 1 & 2)

9.15-9.45 AM KEY NOTE ADDRESS BY PAUL HUCKLE, SENIOR VICE PRESIDENT, GLOBAL REGULATORY AFFAIRS, GLAXOSMITHKLINE (HALL 1 & 2)

9.45-10.15 AM KEY NOTE ADDRESS BY ADRIAN MCKEMEY, PRACTICE LEADER, PRODUCT DEVELOPMENT & COMMERCIALIZATION, QUINTILES (HALL 1 & 2)

10.30-11.30 AM TEA BREAK, POSTER AND EXHIBIT VISIT (HALL 5 & 6)

11.30 AM-1.00 PM CONCURRENT SESSIONS

SESSION 1 - DISCOVERY 1

Target Discovery (G.01)

SESSION CHAIR

V. N. Balaji
Consultant
Discovery Research

Applications of Next Generation Sequencing and Genomics—from Target Discovery to Clinical Trials and Beyond
Raja Mugasimangalam
Founder and CEO
Genotypic Technology

Distilling Omics Data for Drug Discovery
Kalpana Krishnaswamy
Founder and CEO
Metaome Science Informatics

Homology Modeling of Proteins and Ligand Docking: How close are we to drug discovery?
R. Sowdhamini
Associate Professor
National Centre for Biological Sciences

SESSION 2 - COMMERCIALIZATION 1

Health Economics and Valuation (Hall 1 & 2)

SESSION CHAIR

Shashidhar Rao
Head Global Medical Affairs and HEOR
India Operations
Novartis Healthcare

New Molecules: Paths to their Development and Commercialization in India
Nidhi Saxena
Founder and CEO
Karmic Lifesciences

Personalization and Regulatory Framework
Arun Bhatt
President
Clininvent Research

Approach to Early Phase Health Economics Evaluations
Adrian McKemey
Practice Leader, Product Development & Commercialization
Quintiles

SESSION 3 - TECHNOLOGY & STANDARDS 1

Technology for Personalized Medicine — SOA, the Cloud and the Future (G.02)

SESSION CHAIR

Nikhil Kumar
President
Applied Technology Solutions, Inc.

War on Drug Failure & Key Role of Information Technology
Dnyanesh Limaye
Professor and HoD - Pharmacology
Oriental College of Pharmacy
Mumbai University

Pharma and CRO Industries adoption of SOA, SaaS and Cloud Technologies — Key Success Factors
Raghu Punnamraju
Director, Clinical Trials Management Systems Engineering and PI Technology
Perceptive Informatics (A PAREXEL Company)

Technology for Personalized Medicine and the Pharmaceutical Industry
Nimita Limaye
Vice President, Biometrics & Medical Writing
Tata Consultancy Services
Nitin Kumar
Intern
Applied Technology Solutions, Inc.

1.00-2.00 PM NETWORKING LUNCH - POSTER AND EXHIBIT VISIT

2.00-3.30 PM CONCURRENT SESSIONS

SESSION 4 - DEVELOPMENT 1

Public Knowledge and Perceptions as Drivers or Barriers to the Future of Clinical Research in India (G.01)

SESSION CHAIR

Larisa Nagra Singh
Vice President
Global Functional Resourcing, Asia
Quintiles, Singapore

PARTAKE Program and Survey of Public Knowledge and Perceptions of Clinical Research
Larisa Nagra Singh
Vice President
Global Functional Resourcing, Asia
Quintiles, Singapore

Challenges of Drug Development in India – The Relevance of Public Awareness and Partnership
Krathish Bopanna
President and CEO
Semler Research

The Role of Stakeholder Collaborations in the Ethical Conduct of Clinical Research
Nandini Kumar
Former Deputy Director General
Senior Grade Investigator NIH project
National Institute of Epidemiology

SESSION 5 - COMMERCIALIZATION 2

Product and Pricing Strategy and Payor Challenges (G.02)

SESSION CHAIR

Ranga Iyer
Healthcare Consultant

Sizing the Opportunity, Market Driven Commercialization of Products
Dhananjay Bakhle
Executive Vice President, Medical Research
Lupin Pharmaceuticals

Pricing and Access Strategies
Ranga Iyer
Healthcare Consultant

Using Real World Evidence to Drive Access Strategies
Simu Thomas
Global Head, HE&OR Modeling &
Executive Director, Health Economics &
Outcomes Research
Novartis Healthcare, USA

SESSION 6 - OUTSOURCING 1

Outsourcing Strategy (Hall 1 & 2)

SESSION CHAIR

Baljit (Boo) Samra
Corporate Vice President &
Country Manager, India
PAREXEL International

Evolution of Outsourcing Models in Clinical Research
Joseph C. Avellone
Corporate Senior Vice President
Clinical Research Services, Worldwide
PAREXEL International

Outsourcing Challenges and Ethical Practices
Raj Sinha
Director, Global Functional Resourcing
Quintiles

Trends in Early Phase Outsourcing
Mukesh Kumar
Director & Clinical Research Lead,
AP Disease Profile
Therapeutic Strategy Unit
Asia Pacific R & D
Sanofi

3.30-4.30 PM TEA BREAK, POSTER AND EXHIBIT VISIT

4:30-6:00 PM CONCURRENT SESSIONS

SESSION 7 - REGULATORY 1

Regulatory, Ethical & Social Policy Issues in Personalized Medicine: Discovery to Clinic (Hall 1 & 2)

SESSION CHAIR

Carol Isaacson Barash
Principal, Helix Health Advisors
Adjunct Prof. Personalized Medicine
Regis College

Bridging the Gap: Co-Development of Targeted Therapeutics and Companion Diagnostics in the US and Europe
Patrick Larcier
Clinical Development & PV
Voisin Consulting

Ethical Issues: Indian Scenario
Arun Bhatt
President
Clininvent Research

Personalized Medicine, Data Needs & Bumping Up Against Ethics
Carol Isaacson Barash
Principal, Helix Health Advisors
Adjunct Prof. Personalized Medicine
Regis College

SESSION 8 - LEAN SIX SIGMA 1

Lean Six Sigma — Pharmacovigilance, Site Performance and Clinical Operations (G.01)

SESSION CO-CHAIRS

Nimita Limaye
Vice President
Tata Consultancy Services

Helle Gawrylewski
Senior Director, Regulatory Medical Writing
Janssen R&D Companies of J&J, USA

Applying Lean Methodology in Pharmacovigilance
Dinesh Kasthuril
Director, Safety and Risk Management
Sciformix

Improving Process Efficiencies in Clinical Operations — The Lean Approach
Guy Schiller
Vice President, Business Process Excellence
PAREXEL International

Lean Sigma: Improving Site Performance Using Continuous Process Improvement Methods is Key to Sustained Clinical Development
Suresh Ramu
Co-founder and CEO
Cytespace Research

SESSION 9 - PV 1

Patient Safety - A Well Rounded View from the Stakeholders (G.02)

SESSION CHAIR

Vivek Ahuja
Director, Pharmacovigilance - Asia Pacific
Baxter Healthcare

Outsourcing Pharmacovigilance Services: Why India can/cannot be the World Leader
(TBC)

Pharmacovigilance Challenges and Complexities in Global Clinical Trials
Sanjeev Miglani
Vice President
Pharmacovigilance & Medical Writing
Accenture

Understanding the Concept of 'Pharmacovigilance sans Frontières' to Ensure Effective Patient Safety
Vivek Ahuja
Director, Pharmacovigilance - Asia Pacific
Baxter Healthcare

6.00 PM DAY END

9.00-10.30 AM CONCURRENT SESSIONS

SESSION 10 - DISCOVERY 2

Lead Discovery (G.01 & G.02)

SESSION CHAIR

Raman Govindarajan
Head R&D
Sanofi

Impact of Structural Biology on Drug Discovery
Ajith Kamat
Head, Strategic Research Partnerships
Pfizer

Lead Identification and Optimization in Small Molecular Drug Discovery: SBDD Case Studies
Vellarkad N. Viswanadhan
Vice President
Jubilant Biosys

Application of Parallel Medicinal Chemistry Strategies for Rapid and Efficient Optimization of Adenosine A1 Receptor Modulators
(TBC)

SESSION 11 - COMMERCIALIZATION 3

Go to Investors (G.03 & G.04)

SESSION CHAIR

R. B. Smarta
Founder and Managing Director
Interlink Marketing Consulting

Mergers or Partners
D A Prasanna
Chairman and Managing Director
Ecron Acunova

Branding: An Essential Tool to Attract Investment
Madeline Ducate
Executive Vice President, Global Operations
Pharm-Olam International

Funding and Investing in New Product Development
Anil Kamath
Founder Chairman
Esemcee Advisors

SESSION 12 - MANUFACTURING 1

Quality Management in Manufacturing (G.05 & G.06)

SESSION CHAIR

Sunil Singhai
Vice President - Tech Transfer
Dr. Reddy's Laboratories

Potent Product Process and Facility Design
Sunil Singhai
Vice President - Tech Transfer
Dr. Reddy's Laboratories

Quality Management Process in Facility Development
Vinay Nayak
President
Alembic Pharmaceuticals

World Class Manufacturing- A Challenge and Opportunity for the Indian Pharma Industry
Pushpinder Bindra
CEO
Zenith and Beyond

Case Study: Integration of Patient Needs, and Quality Requirements in Recent Times has Enforced Application of "Quality by Design (QbD)" and "Process Analytical Technology (PAT)" to development of Therapeutic Vaccines
Nicolas Cappuccino
Global Head, Quality
Dr. Reddy's Laboratories

10.30-11.30 AM TEA BREAK AND EXHIBIT VISIT

11.30 AM-1.00 PM CONCURRENT SESSIONS

SESSION 13 - DEVELOPMENT 2

Evolving Roles of Personnel Involved in Clinical Trials — Panel Discussion (G.01 & G.02)

SESSION CHAIR

Sam Mathew
Process Lead-Medical Writing
Accenture Services

Ajit Nair
Global Head - Clinical Services
Tata Consultancy Services

Partha Chakraborthy
Senior Director & Global Delivery Head, R&D
Cognizant Technology Solutions

Shubhadeep Sinha
Head (Global) & Associate Vice President
Clinical Development & Medical Affairs (CD&MA)
Hetero Group

SESSION 14 - LEAN SIX SIGMA 2

Lean Six Sigma — Medical Writing (G.03 & G.04)

SESSION CO-CHAIRS

Nimita Limaye
Vice President
Tata Consultancy Services

Helle Gawrylewski
Senior Director, Regulatory Medical Writing
Janssen R&D Companies of J&J, USA

Panel Discussion - Thinking Lean in Medical Writing: Driving Change...

Paul Sokol
Senior Director
Neuroscience Therapeutic Area Head Reg MW
Janssen Research & Development PRD

Shashidhar Rao
Head Global Medical Affairs and HEOR, India Operations
Novartis HealthCare

Offshoring Medical Writing: Lean Project Management Strategy

Paul Sokol
Senior Director
Neuroscience Therapeutic Area Head Reg MW
Janssen Research & Development

Seema Gurbani
Assistant Manager
Tata Consultancy Services

Improving the Sigma Level of Medical Writing

Shashidhar Rao
Head Global Medical Affairs and HEOR, India Operations
Novartis Healthcare

Murthy Palli
Operations Manager
Novartis Healthcare

SESSION 15 MANUFACTURING 2

Personalized medicine and challenges ahead for Biomanufacturing in India (G.05 & G.06)

SESSION CHAIR

Subir Basak
President
Jubilant Biosys

Pharmacogenomics for Personalized Medicine: Optimizing use of Drug and Drug Combinations to Improve Patient Outcome

Jugnu Jain
Director
Saarum Siences

Quality Control, a Necessary Paradigm when 'Leaning Out' Operations, as Pharmaceuticals Shift from the Blockbuster Model to Personalized Gene Therapies and Gene-specific Small-molecule Treatments

Swapnil Ballal
Quality Lead
Biocon

BioManufacturing in India

Subir Basak
President
Jubilant Biosys

1.00-2.00 PM NETWORKING LUNCH AND EXHIBIT VISIT

2.00-3.30 PM CONCURRENT SESSIONS

SESSION 16 - DISCOVERY 3

Pre-clinical Discovery and Development (G.01 & G.02)

SESSION CHAIR

Vishwanath Iyer (Mahesh)
Head, Oncology Biometrics
Novartis Healthcare

Translational Approaches to Target Validation, Drug Action and Patient Response Characterization
Raman Govindarajan
Head, R&D India
Sanofi

Imaging as a Biomarker In Early Stage Development
Smita Pandit
Director, Imaging Operations
Perceptive Informatics (A PAREXEL Company)

Pharmacovigilence and Drug Safety
Shwetha Kamath
Drug Safety Physician
Accenture

SESSION 17 - REGULATORY 2

Scientific, Regulatory and Ethical Challenges in Advancing Personalized Medicine (G.03 & G.04)

SESSION CHAIR

Carol Isaacson Barash
Principal, Helix Health Advisors
Adjunct Prof. Personalized Medicine
Regis College

Realizing the Promise of Personalization through Healthcare Mass Commercialization
Sagar Kamarthi
Associate Professor
Department of Mechanical and Industrial Engineering
Northeastern University, Boston

Regulatory Challenges for Molecular and Companion Diagnostics
Jeffrey N. Gibbs
Director
Hyman, Phelps & McNamara, P. C.

Ethical Issues in Individualized Health Care — Seeking Solutions in a Complex World
Aamir Shaikh
Founder
Assansa

Personalized Nutrition: Parallels from Personalized Medicine
Emanuelle Voisin
CEO and Principal
Voisin Consulting

SESSION 18 - TECHNOLOGY & STANDARDS 2

Data and Semantic Interoperability in Personalized Medicine (G.05 & G.06)

SESSION CHAIR

Nikhil Kumar
President
Applied Technology Solutions, Inc., USA

Semantic Interoperability, Data and Personalized Medicine
Nikhil Kumar
President
Applied Technology Solutions, Inc., USA

CDASH Standards Library Implementation Across Multiple EDC Systems and its Potential Benefits
Sunish Raj
Manager, GRO
PAREXEL International

Harmonization of Clinical Data Standards
Senthil Raja
Manager, Clinical DB Programming
PAREXEL International

3.30- 4.30 PM TEA BREAK AND EXHIBIT VISIT

4:30-6:00 PM CONCURRENT SESSIONS

SESSION 19 - DEVELOPMENT 3

Current Challenges in Clinical Development in India (G.01 & G.02)

SESSION CHAIR

Vishwanath Iyer (Mahesh)
Head, Oncology Biometrics
Novartis Healthcare

Challenges in conducting Clinical trials in India: Sponsor's perspective
Bobby George
Asst Vice President & Head Regulatory Affairs
Reliance Life Sciences

Finding New Drugs for the Treatment of Neglected Diseases: Trials and Tribulations
T Balganesh
Distinguished Scientist Head of OSDD unit
Council of Scientific and Industrial Research (CSIR)

Current Ethics related Challenges in Clinical Development in India
Shoibal Mukherjee
Vice President and Head
Asia Medical Sciences Group
Quintiles

SESSION 20 - THERAPEUTICS 1

Therapeutics — Pharmacology and Applications in Personalise Medicine (G.03 & G.04)

SESSION CHAIR

Vishwas Sovani
Country Manager
Revogenex, Inc.

Personalised Medicine Pharmacological basis
Vishwas Sovani
Country Manager
Revogenex, Inc.

Therapeutic Applications of Personalized Medicine
Mangesh Kulkarni
Group Head, DS&E
Novartis Healthcare

Ready to use Kits for Personalized Medicine
Mukesh Agrawal
Vice President, CRL
Vimta Labs

SESSION 21 - MANUFACTURING 3
PANEL DISCUSSION

Panel Discussion on Regulatory in Manufacturing (G.05 & G.06)

PANELISTS

Regulators Invited

6.00 PM DAY END

9:00-10:30 AM CONCURRENT SESSIONS

SESSION 22 - DEVELOPMENT 4

Shifting Paradigms in Clinical Research (G.01 & G.02)

SESSION CHAIR

Y. K. Gupta
Prof. & HoD, Department of Pharmacology & Nephrology,
AIIMS

Design of Drug Clinical Trials Incorporating a Companion Diagnostic
Rajashree Devarakonda
Director
Voisin Consulting

The Prospect of Microdosing Trials in India
Y. K. Gupta
Prof. & HOD, Department of Pharmacology & Nephrology
AIIMS

Private-Academic Collaborations in Clinical Research: An Emerging Paradigm
Sanjay Mittal
Director - Research and Clinical Cardiology
Medanta - The Medicity

10.30- 11.30 AM TEA BREAK AND EXHIBIT VISIT

11.30 AM-1.00 PM CONCURRENT SESSIONS

SESSION 23 - DEVELOPMENT 5

Current Topics in Biostatistics (G.01 & G.02)

SESSION CHAIR

Munish Mehra
President
Global Alliance of Indian Biomedical Professionals, USA

Development and Validation of Threshold-based Prognostic and Predictive Biomarker Signatures for Personalized Medicine Strategy
Arunava Chakravartty
Data Sciences Team Leader, Asia
Unilever R&D.

Dealing with Multiplicity Issues When Assessing Benefit in Targeted Sub-populations - A Case Study
Vishwanath Iyer (Mahesh)
Head, Oncology Biometrics
Novartis Healthcare

Best Practices in Handling of Missing Data Including Use of Method of Multiple Imputations
Munish Mehra
President
Global Alliance of Indian Biomedical Professionals

SESSION 24 -TECHNOLOGY & STANDARDS 3

GRC (Governance, Regulation & Compliance) and Personalized Medicine (G.03 & G.04)

SESSION CHAIR

Nikhil Kumar
President
Applied Technology Solutions, Inc, USA

GRC and Personalized Medicine - The Evolving Impact of HIT and Personalized Medicine on GRC and its Implications
Nikhil Kumar
President
Applied Technology Solutions, Inc., USA

Complete Outsourced Pharmacovigilance Operations, Database and Reporting 24x7 Available Interaction Center
Femida Gwadry-Sridhar
Director, Health Informatics
Lawson Health Research Institute

Technical Challenges in Large Safety Implementation
Anjani Kumar Jha
Director
November Research Group

1.00-2.00 PM NETWORKING LUNCH AND EXHIBIT VISIT

2.00-3.30 PM CLOSING PLENARY SESSION

Personalized Precision Medicine: Regulatory, Financial and Ethical Challenges to Ensuring its Growth (G.01 to G.04)

SESSION CHAIR

Carol Isaacson Barash
Principal, Helix Health Advisors
Adjunct Prof. Personalized Medicine, Regis College

Regulatory Pitfalls in Getting IVDs and Companion Diagnostics
FDA Approved Communication with the FDA

Jeffrey N. Gibbs
Director
Hyman, Phelps & McNamara, P. C.

Arun Mishra
Director, Global Regulatory Affairs
Asia-Pacific, Japan, Emerging Markets
GlaxoSmithKline

Shoibal Mukherjee
Vice President and Head
Asia Medical Sciences Group
Quintiles

Nandini Kumar
Former Deputy Director General
Sr. Grade Investigator NIH project
National Institute of Epidemiology

Femida Gwadry-Sridhar
Director, Health Informatics
Lawson Health Research Institute

Sagar Kamarthi
Associate Professor
Department of Mechanical and Industrial Engineering
Northeastern University, Boston

REGISTRATION FORM/ INVOICE

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CANCELLATION POLICY: CANCELLATIONS MUST BE IN WRITING AND RECEIVED ON OR BEFORE SEPTEMBER 30, 2012.

Registrants who do not cancel in writing by that date and do not attend the event will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. If the event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants. **Upon cancellation, the administrative fee that will be withheld is: Industry - INR 6,000 | Academia/ Student - INR 3,500 | Tutorial - INR 3,371.**

(All refunds will be issued in the currency of original payment.)

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Excellent opportunity to interact and network with the largest gathering of International and Indian Regulators and Pharma professionals in India. To know more on the this exhibit & showcase your products and services contact Manoj.Trivedi@DIAIndia.org or call +91.98.1977.7493

REGISTRATION PROCESS

Registration form should be duly filled and signed by the authorized person. You are requested to email the duly filled and signed registration form to **rhean.dsouza@diaindia.org** first and then courier it along with registration fees within 5 working days. All registrations alongs with the registraion fees should reach DIA (Mumbai office) before the conference. For clarifications call Rhean D'Souza on +91.98205.87798

DELEGATE DETAILS

(Please write all details in full caps)

Please check the applicable category:

❑ 3 Days | ❑ 2 Days - ❑ Nov 2nd ❑ Nov 3rd ❑ Nov 4th

❑ Academia ❑ Government ❑ Industry ❑ CRO ❑ Non-Member ❑ Member : Customer ID No.: _____

❑ Dr. ❑ Mr. ❑ Ms. First Name Last Name (Family Name) .

Job Title Organisation/ Company/ Institute Name

Address (Please write your address in the format required for delivery to your country.) ❑ Business Address ❑ Home Address

Postal Code City State Country

Telephone Number Fax Number Mobile Number

email (Required for confirmation) Authorised Signatory

Payment contact person's Full Name Telephone Number Email

Organisation PAN no. **TOTAL PAYABLE AMOUNT**

PAYMENT INFORMATION

BANK DETAILS:

Beneficiary Account Number : 061010200024611
Name of Account : DIA (India) Pvt Ltd
Bank Name: AXIS BANK LTD.
Bank Address: Dhiraj Baug Near Hari Niwas Circle, LBS Marg, Thane (West) – 400602, Maharashtra, INDIA
Swift Code: AXISINBB061
IFSC CODE : UTIB0000061
Service Tax Registration #: AACCD8624N ST001
Permanent Account (PAN) # : AACCD8624N

CHEQUE DETAILS:

Please send the completed form, along with draft/cheque made payable to **DIA (India) Private Limited** to: Rhean D'Souza, DIA (India) Private Limited A-303, Wellington Business Park, Andheri-Kurla Road, Marol, Andheri (East), Mumbai 400 059 India. Phone: +91.22.6765.3226

MEETING CONTACTS

MEETING MANAGER: Manoj Trivedi, Senior Manager Marketing and Program Development, DIA (India) Private Limited
Cell: +91.98.1977.7493, Tel: +91.22.6765.3226, mail: Manoj.Trivedi@diaindia.org

HOTEL RESERVATIONS

Attendees are responsible for their hotel & airline reservations. Novotel & HICC Complex is holding a block of rooms at the reduced rate mentioned below until September 30, 2012, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single INR 7500 (Inclusive of taxes and breakfast)

CONTACT: Burzin Patel

email: bkpatel@hicc.com
Tel: +91.40.6613.4422; Fax: +91.40.6613.4322
Add: Novotel & HICC Complex (near Hitec City), PO Bag 1101, Cyberabad Post Office, Hyderabad - 500 081