5th Annual Conference on Drug Discovery and Clinical Development:

Meeting the Challenges of Next Generation R&D – Enhancing Efficiency, Effectiveness and Innovation

* TUTORIALS:

October 23, 2010
HOTEL LE MERIDIAN
No. 28, Sankey Road
Bangalore, India

CONFERENCE:

October 24-26, 2010
HOTEL THE LALIT ASHOK
Bangalore, India

*** PLEASE NOTE — *SEPARATE VENUES***
Tutorials are taking place at
THE HOTEL LE MERIDIAN.

The Conference is taking place at
HOTEL THE LALIT ASHOK.

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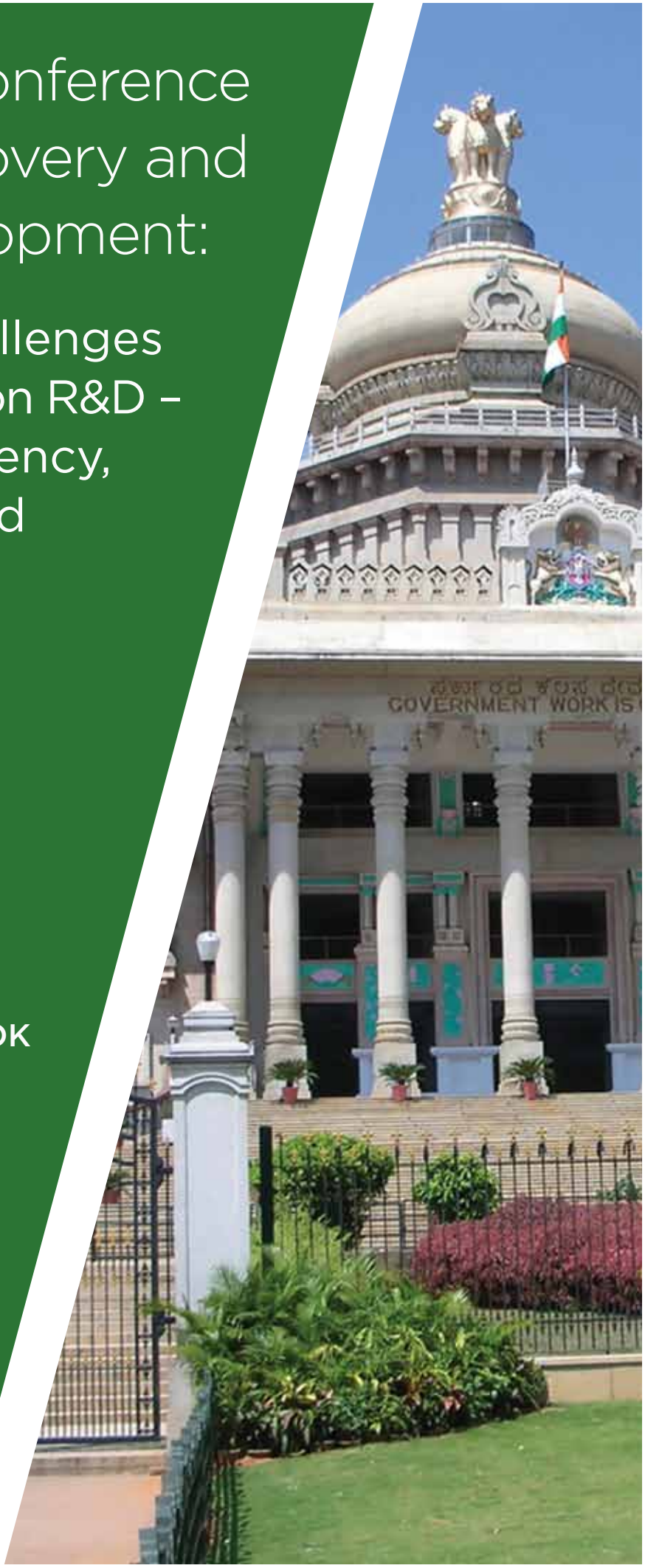

5th Annual Conference on Drug Discovery and Clinical Development

Tutorials: October 23, 2010

Hotel Le Meridian | Bangalore, India

Tutorial Instructors

John Marx
Lorenz Lifesciences, Germany
TUTORIAL #1

Jayaprakash Nallasamy
Lorenz Lifesciences India
TUTORIAL #1

William Sietsema
University of Cincinnati, USA
TUTORIAL #2 & #7

Elke Sennewald
Kendle International
TUTORIAL #2

Abdullah Hassen
Health Authority, Abudhabi
TUTORIAL #3

Arun Mishra
GSK, UK
TUTORIAL #3

Ramanan Dayalan
Clinical Data Operation, Take Solutions Ltd., Chennai
TUTORIAL #4

Ganesh Sankaran
Take Solutions Ltd., Chennai
TUTORIAL #4

Shiva Murthy N
Quartesian CR P. Ltd.
TUTORIAL #5

Srinivas Sidgiddi
Connexios Life Sciences, Bangalore
TUTORIAL #5

Sushrut Bhatt
GSK
TUTORIAL #6

Avinash Babu Bonu
Aris Global
TUTORIAL #6

Bhajish Bharathan
Provenance Research India
TUTORIAL #6

Nagalakshmi Padmanabhan
Consortium Clinical Research
TUTORIAL #6

Nayan Nanavati
Consultant
TUTORIAL #7

Mubarak Naqvi
sanofi-aventis
TUTORIAL #8

PHOTO NOT AVAILABLE

Sheila Weir
Newron Pharmaceuticals
TUTORIAL #8

PHOTO NOT AVAILABLE

Munaf Ali
Consultant
TUTORIAL #8

Tutorial Registration

MORNING: 8:00-9:00 AM **AFTERNOON:** 12:00-1:00 PM

Pre-Conference Workshop / Tutorials

MORNING TUTORIALS — 9:00 AM-1:00 PM

#1 Moving from CTD to eCTD — Some Practical Considerations

#2 Adaptive Clinical Trials — Overview of Adaptive Elements in Trial Design and Analysis

#3 Regulatory Perspective of Clinical Trials and Clinical Supplies

#4 CDISC STDM Standards

AFTERNOON TUTORIALS — 2:00 PM-6:00 PM

#5 Biosimilars — Prospects and Challenges in the Development, Licensing, and Commercialization

#6 Current Practices In Pharmacovigilance and Risk Management in Drug Safety Surveillance

#7 Overview of Clinical Development Planning

#8 Advanced Project Management

DIA would like to thank all the instructors for their support and active participation.

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MORNING TUTORIALS — #1 - #4 — 9:00 AM-1:00 PM

TUTORIAL WORKSHOP #1

Moving from CTD to eCTD: Some Practical Considerations

OVERVIEW

- Introduction to eCTD, CTD to eCTD transition
- Discussion on eCTD structure – modules 1 to 5, folder structure, node attributes, leaf element, regional xml file
- Preparing your first eCTD submission – style sheet, ICH and regional DTDs, MD5, checksum, index.xml file
- Preparing your first eCTD submission – submission plan preparation, document preparation, bookmarks, hyperlink, compilation, publishing, validation
- Module 1 differences for US, EU, CA and Switzerland – sample eCTD to US FDA, DMF and ASMF preparation in eCTD with live demonstration
- Study tagging file preparation for clinical/nonclinical studies

TUTORIAL WORKSHOP #2

Adaptive Clinical Trials: Overview of Adaptive Elements in Trial Design and Analysis

OVERVIEW

- Review of adaptive design trial types – general overview of the types of adaptations that can be considered along with the benefits and disadvantages
- Statistical methods in adaptive trial designs – focus on statistical approaches used in some of the key adaptive trial design options
- Regulatory considerations in adaptive trial designs – what adaptations are considered acceptable to regulatory agencies and how such plans are best shared and negotiated with agencies
- Hands-on workshop – participants to draft their own adaptive designs with consultation and discussion with the course coordinators

TUTORIAL WORKSHOP #3

Regulatory Perspective of Clinical Trials and Clinical Supplies

OVERVIEW

- Clinical development and clinical trials in emerging markets
- High-level clinical trial regulatory framework in emerging markets
- Clinical trial regulatory path in Canada, US, and Europe

TUTORIAL WORKSHOP #4

CDISC STDM Standards

OVERVIEW

- Participants will be given CRF and asked to identify SDTM domains and annotate the same
- Trial design domain concepts, SUPPQUAL, RELREC, Dataset, with example
- Participants will be asked to perform an exercise identifying custom domains and their general observation classes

continued on next page

AFTERNOON TUTORIALS — #5 - #8 — 2:00 PM-6:00 PM

TUTORIAL WORKSHOP #5

Biosimilars: Prospects and Challanges in the Development, Licensing, and Commercialization

OVERVIEW

Participants of this tutorial will learn differences in development of generics and biosimilars, challenges associated with development of biosimilars, advantages of developing biosimilars in India, readiness of CROs to support biosimilars development.

They will also have fair understanding of responsibilities of investigators, patients, physicians, and pharmacists in recommending appropriate use of biosimilars.

Attempts will be made to provide approval processes of biosimilars in India, US, EU regions, and a few interesting case studies relevant to biosimilars development will be discussed.

TUTORIAL WORKSHOP #6

Current Practices in Pharmacovigilance and Drug Risk Management

OVERVIEW

Contextual understanding of pharmacovigilance in the clinical trial setting

- Various clinical trial regulations peratining to PV
- Case studies
- CIOMS and MedWatch forms
- Causality, seriousness, and expectedness assessments
- Indian regulations, ground realities and the way forward

TUTORIAL WORKSHOP #7

Clinical Development Planning

OVERVIEW

In this tutorial, participants will receive a comprehensive overview of the process used by major pharmaceutical companies for mapping out a clinical development program.

Topics will include some basic pase 1, 2, and 3 study designs, selection of controls, and pediatric and geriatric studies.

- Overview of clinical development planning
- Phase 1 trial designs
- Phase 2 and 3 trial designs
- Selection of controls
- Special population studies – pediatric and geriatric
- Organ impairment studies

TUTORIAL WORKSHOP #8

Advanced Project Management

OVERVIEW

This tutorial will provide the participants with a detailed conceptual knowledge of project management in clinical drug development. The tutorial will cover the concepts of project management as they are applicable in clinical drug development, the project manager's role in the drug development cycle from early clinical development through phase 2 and 3 clinical research and eventual registration.

- Developing a robust clinical development plan
- Role and importance of the project manager in end-to-end clinical development
- Planning and execution of early clinical development
    * Transition from bench to bedside: best practices for incorporating
      translational research
    * Where to conduct phase 1 studies – managing costs and timelines
    * Regulatory aspects specific to early clinical development
- The project manager's role in planning and execution of phase 2 and 3 studies
- Quality management through the entire clinical development
- Putting together the product dossier for submission to health authorities

5th Annual Conference on Drug Discovery and Clinical Development:

Conference: October 24-26

Hotel The Lalit Ashok | Bangalore, India

PROGRAM COMMITTEE

Mubarak Naqvi
Director, Clinical Research, Sanofi-Aventis, India

Suresh Bowalekar
Managing Director, Pharmanet, India

Nandini Kumar
Former Deputy Director General Senior Grade

Moin Don
Associate Director, Johnson & Johnson, India

Albinus D'Sa
Deputy Country Director, USFDA, India

Munish Mehra
Managing Director, Global Drug Development Experts, USA

Nigel McBean
Vice President & Director Operations, IndiPharm, India

Nandkumar Chodankar
Group CEO, Pharma Business Excel Industries, India

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Director Operations, ClinTec, India

Babu Nema
Head, Pharma Innovation, TCS, India

Ramesh Jagannathan
Associate Director, AstraZeneca, India

Katta Ramanjaneya
Managing Director, SMO-India

Chandrashekhar S.
Director, Bigtec Labs, India

Jayanti Gupta
VP, Clinical Development Semler Research Center, India

Gurudatta GG
Chief Operating Officer, Semler Research Center, India

Sowmyanarayanan Srinivasan
Consulting Manager-Discovery Informatics, Cognizant, India

****Tutorials on October 23, 2010, will take place at Le Meridien Hotel, Bangalore, India.**

DIA (India) Private Limited
A 303, Wellington Business Park I
Marol Andheri-Kurla Road
Andheri (East), Mumbai - 400059

KEYNOTE SPEAKERS

Lakshmi Narayanan
Vice Chairman
Cognizant

Purvish Parikh
Managing Director
Americares India

SPECIAL GUEST

Bharatesh Jagashetty
Drug Controller, Karnataka
India

Hasit Joshipuyr
Vice President-South Asia
GlaxoSmithKline

Abhijai Barwe
Chief Operating Officer
Clingene International, Ltd.

Sri Mosur
CEO, President and MD
Jubilant Biosys

Rama Mukherjee
Managing Director
ARA Health

Rajiv Ranjan
Executive Vice President & Global Head - Business Operations
Patni Computer Systems

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THEME ADVISORS

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Radhika Bobba
Director-Medical Services
Stempeutics Research

Urmila Thatte
Seth GS Medical College

Annabelle Rajaseheran
Professor, Member Secretary
at CARE Independent Ethics Committee

SESSION MODERATORS

Nimish Vachharajani
Senior Vice President
Advinus Therapeutics

Kathy Heard
Deputy Director, Head of
Study Management
Sanofi Pasteur

Suresh Bowalekar
Managing Director
PharmaNet

Munish Mehra
CEO
Global Drug Development

Suresh Ramu
Vice President & Head-India
Clinical Development
Services

Alberto Grignolo
PAREXEL Consulting

Mubarak Naqvi
Sanofi Aventis

Emmanuelle Voisin
Voisin Consulting Life
Sciences

Nandini Kumar
Former Deputy Director
General Senior Grade

Nayan Nanavati
Consultant

Vis Niranjan
President
RxMD

Brigitte Franke-Bray
Director
DIA, Europe

CxO CONCLAVE MODERATOR

Gauri Kamath
Senior Editor
Business World

PROGRAM CO-CHAIRS

Balasubramanian Sankaranarayanan
Practice Director
Cognizant, India

Krathish Bopanna
President and
Executive Director
Semler Research Center

Larisa Nagra Singh
Voisin Consulting Life
Sciences

Conference Topics:

- Drug Discovery
- Regulatory Affairs
- Early / Pre-Clinical Development
- Clinical Operations
- Quality Assurance and Compliance
- Biologics and Vaccines
- Pharmacovigilance and Drug Safety
- Clinical Data Management, Biostatistics, and Medical Writing
- Central Lab Management
- Clinical Trial Logistics / Supplies

About Drug Information Association (DIA)

DIA is a professional association of approximately 18,000 members worldwide who are involved in the discovery, development, regulation, surveillence, or marketing of pharmaceuticals or related products. DIA is committed to the broad dissemination of information of new medicines or generics or biosimilars with continously improved professional practice as a goal.

DAY 1 | SATURDAY, OCTOBER 23

4.00PM -6.00 PM CONFERENCE REGISTRATION

Hotel Lalit Ashok, Bangalore, India

8.00 AM- 10.00 AM TUTORIAL WORKSHOP REGISTRATION

Le Meridien, Bangalore, India

09.00 AM-01.00 PM TUTORIAL WORKSHOPS #1 TO #4

#1 Moving from CTD to eCTD
Some Practical Considerations

John Marx

Jayprakash Nallasamy

Lorenz Germany

#2 Adaptive Clinical Trial
Overview of Adaptive Elements in Trial Design and Analysis

William Sietsema

University of Cincinnati, USA

Elke Sennewald

Kendle International

#3 Regulatory Perspective of Clinical Trials and Clinical Supplies

Abdullah Hassen

Health Authority, Abudhabi

Arun Mishra

GSK, UK

#4 CDISC STDM Standards

Ganesh Sankaran

Take Solutions

Ramanand Dayalan

Take Solutions

01.00 PM-2.00 PM LUNCH BREAK

02.00 PM-6.00 PM TUTORIAL WORKSHOPS #5 TO #8

#5 Biosimilars
Prospects and Challenges in the Development Licensing and Commercialization

Shiva Murthy N

Quartesian CR P. Ltd.

Srinivas Sidgiddi

Connexios Life Sciences

#6 Current Practices In Pharmacovigilance and Drug Risk Management

Nagalakshmi Padmanabhan

Consortium Clinical Research Pvt. Ltd.

Sushrut Bhatt

GSK

Bhajish Bharathan

Provenance Research India

Avinash Bonu

Aris Global

#7 Clinical Development Planning

William Sietsema

University of Cincinnati, USA

Nayan Nanavati

Consultant

#8 Advanced Project Management

Mubarak Naqvi

Sanofi Aventis

Sheila Weir

Newron Pharmaceuticals

Munaf Ali

Consultant

DAY 2 | SUNDAY, OCTOBER 24

7.30 AM -11.00 AM CONFERENCE REGISTRATION

9.00 AM-10.30 AM OPENING CEREMONY

Keynote Speaker

Lakshmi Narayanan

Vice Chairman, Cognizant

Purvish Parikh

Managing Director Americares India

10.30 AM-11.00 AM REFRESHMENT BREAK/ EXHIBITORS VISITS

11.00 AM-1.00 PM SESSION I

CxO Conclave — India, the Emerging Pharmaceutical Powerhouse

The global Pharmaceutical Industry is at an inflection point today. While the core objective of the industry still remains safe & effective treatments, greater access to affordable healthcare and superior product quality including increasing costs of drug discovery & regulatory environment that is still maturing in many parts of world. Leaders from Industry at this DIA CxO Conclave would be focussing on India as a preferred destination for services as well as large untapped market for global pharmaceutical organizations.

A brief presentation of Key Speakers will be followed by a panel discussion.

Moderator

Gauri Kamath

Senior Editor, Business world

Panel

Hasit Joshipura

VP, GSK

Shailesh Ayyangar

MD, Sanofi Aventis

Abhijit Barwe

COO Clingene

Deepak Khosla

President SAARC, Patni Computer Systems

Sri Mosur

CEO, President & MD Jubilant Biosys, India

Rama Mukherjee

Managing Director, ARA Health

Manni Kantipudi

President GVK - Bio

1.00 PM-2.00 PM LUNCH BREAK/ EXHIBITORS VISITS

2.00-5.30 PM SESSION II

Innovation or Stagnation - Integrating Innovation in the Corporate culture of Drug Discovery and Development

Starting 2004, the FDA issues several documents indicating "the reasons for the widening gap between scientific discoveries that have unlocked the potential to prevent and cure some of today's biggest killers, such as diabetes, cancer, and Alzheimer's, and their translation into innovative medical treatments." Innovation in all aspects of drug discovery and development is critical to overcome the high failure rate, long development times and increasing costs to bring new medical treatments to patients. This session will bring speakers who will share what has been done and what more needs to be done.

Moderator:

Munish Mehra
Global Drug Development

The Critical Path and Duke Clinical Trial Transformation Initaitive to Increase Innovation in Drug Development

Christopher Paul-Milne
Tufts University

Nimish Vachharajani
Advinus Therapeutics

4.00 PM-4.30 PM REFRESHMENT BREAK/ EXHIBITOR VISIT

Panel Discussion

Munish Mehra
Global Drug Development

Christopher Paul-Milne
Tufts University

Nimish Vachharajani
Advinus Therapeutics

Brigitte Franke-Bray
DIA European Office

DAY 3 | **MONDAY, OCTOBER 25**

CONCURRENT SESSIONS

09.00AM-10.30 AM SESSION III (GRAND BALLROOM)

Metrics and Benchmarking: Why They are Important in Today's Clinical Operations Organisation

The Pharmaceutical/Biotechnology Industry over last 5-10 years has been heavily focused on implementing efficient and effectiveness processes to improve all aspect of their drug development process. The clinical trial process has been one area, with the formation of a non-profit organisation Metrics Champion Consortium to develop global standard performance metrics for implementation by major pharmaceutical and service providers to improve clinical trial performance in the future. Additionally patient enrolment is key factor and majority of the BIG pharma/biotech companies are implementing strategies that help plan, forecast and manage their patient enrolment targets in cost effective manner.

Moderator:

Suresh Ramu
Quintiles, India

Global Initiative: Standardisation of Benchmarking in the Clinical Trial Process
Nicole Lee,
PAG ICON Clinical Singapore

Measuring Productivity in CRO Clinical Operations
Nicole Lee,
PAG ICON Clinical Singapore

Balasubramanyan Sankaranarayanan
Cognizant ,India

09.00AM-10.30 AM SESSION IV (CONVENTION HALL)

Pharmacovigilance and Drug Safety

Moderator:

Nilima Kshirsagar
ESI-PGIMSR MGM Hospital

Proactive Risk Management, Challenges and Collaborative Efforts with Pharma Companies - A Regulator's Perspective

Bhaswat Chakraborty
Cadila Pharmaceuticals, India

The Art of Proactive Pharmacovigilance - An Industry Perspective

Sadhna Joglekar
GSK, India

Drug Safety / Pharmacovigilance KPO - Its Potential, the Future and Anticipated Challenges

Mir Imran Ali
Qunitiles, India

10.30-11.00 REFRESHMENT BREAK

CONCURRENT SESSIONS

11.00- 1.00 SESSION V (GRAND BALLROOM)

Regulatory Challenges: Domestic vs Global

Regulation of drug development is a challenging area when harmonization with global standards would be ideal. Hectic activities are continuing at the office of Drug Controller of India to modernize facilities and resources to meet the challenges of increasing demands on regulation of synthetic drugs besides other forms of formulations that are reaching the Indian market. Monitoring or auditing is being seriously considered by this office. How the industry and the regulators face these challenges would be discussed in this session.

Moderator:

Nandini Kumar
National Institute of Epidemiology

Clinical Trial Inspections : Current Scenario In India
A. K. Pradhan
Deputy DCGI, India

Overview of Drug Regulatory Requirements and Trends
Abdullah Hassen
Health Authority Abudhabi

Regulatory Overview - USFDA India Office
Albinus D'sa
USFDA

11.00- 1.00 SESSION VI (CONVENTION HALL)

Biosimilars

This session will focus on the different stages of 'development' of biosimilars in terms of regulatory framework, marketing authorization and their presence in the EU, US and Indian market. It will also provide overview on the product specific guidelines and the latest news concerning the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) and the Patient Protection and Affordable Care Act (PPAC Act), signed into law this year.

Moderator:

Larisa nagra Singh
Voisin Consulting Life Sciences

Status of Biosimilars in EU and Potential New Development
Emmanuelle Voisin
Voisin Consulting Life Sciences

Biosimilars - An US Perspective
Subir Basak
Celestial Biologicals

Quality Challenges of Biosimilars
Sanjay Shetgar
Dr. Reddy's Laboratories

Estelle Michael
GlaxoSmithKline

1.00-2.00 LUNCH BREAK

CONCURRENT SESSIONS

2-3.30 SESSION VII (GRAND BALLROOM)

GOING FOR BRIC: Evolving Sponsor Strategies and Tactics to Access Emerging Markets and Japan Before or After US and EU Registration

The pharmaceutical world has turned its attention to emerging Markets eg: BRIC (Brazil, Russia, India, and China) Because if this current and anticipated high growth rates compared to American and European Markets. Historically, companies have persued & obtained registration in the US and EU before their attention to Japanese registration. This session will focus on how several companies are approaching Japan and other emerging markets to accelerate drug development and registration in these commercially attractive regions.

Moderator:

Alberto Grignolo
PAREXEL Consulting US

Experiences in Emerging Markets and Japan : Impact on Global Development
Joseph Scheeren
Bayer Healthcare Pharmaceuticals Inc. US

Evolving Sponsor Strategies and Tactics to Access Emerging Markets
Arun Mishra
GSK, UK

Emerging Markets: The Small to Mid-Sized Company Perspective
David Mantus
Cubist Pharmaceuticals, USA

2-3.30 SESSION VIII (CONVENTION HALL)

Medical Writing

In the globalised scenario, accessible, credible peer reviewed publications ad value to clinical practice, contribute to scientific progress, and have the poten tial to exert tremendous influence. Therefore, medical writing which interpret scientific information and disseminates the results of clinical trials fundamenta to evidence-based medicine needs to be applied as an art targeting specifi requirements. Outsourcing and in-sourcing of medical writing have differen requirements for resources for optimal results. In this sessions various aspect of this area will be discussed from academic and industry point of view.

Moderator:

Vis Niranjan
RxMD

Strategies Facilitating Acceptance of a Research Paper: from Submission to Final Decision
Sandeep Bavadekar
TN Medical College & BYL Nair Hospital

Publication Planning: Effectively Using Publications as a Component of the Overall Strategy
Sujata Shah
Sanofi Aventis

Health Writing for the Public: Ensuring Effectiveness
Natasha Das
Consultant

3.30-4.00 REFRESHMENT BREAK

CONCURRENT SESSIONS

4.00-5.30 SESSION IX (GRAND BALLROOM)

Drug Discovery and Early Preclinical Development

In the recent years, there has been a steady development of discovery research in India. A number of NCE's have been registered by Indian companies, or by Indian R&D Units of MNCs. Simultaneously, many Indian Companies have developed robust infrastructure & capabilities for preclinical research as well. This session will evaluate the development of discovery and preclinical research in India.

Moderator:

Mubarak Naqvi
Sanofi Aventis, India

Building Successful Partnerships in Drug Discovery and Development
Ravi Anand
Newron Pharmaceuticals, India

Review of Novel Targets in Malaria / Dengue
Sunil Bhaskaran
Indus Biotech, India

Risk Evaluation and Mitigation Strategies (REMS) : Current Status and Lessons Learned
Nayan Nanavati
Consultant

4.00-5.30 SESSION X (CONVENTION HALL)

Quality Assurance and Compliance

The Globalization and increased complexity of clinical trials makes compliance to international and country specifc requirements a challenge. This session will bring experts to share their experience on Quality Assurance and Compliance in Conducting Clinical Trials in India and globally.

Moderator:

Moin Don
Johnson & Johnson

Investigator Site Audits and GCP Compliance
Shehnaz Vakharia
Consultant

Taking GCP from Compliance to Proactive and Integrated quality risk management

GCPs - Similarities and Differences Worldwide and Practical Do's and Don'ts to avoid Warning Letters
Munish Mehra
GDD Experts USA

DAY 4 | TUESDAY, OCTOBER 26

CONCURRENT SESSIONS

9.00 AM-10.30 AM SESSION XI (GRAND BALLROOM)

Biologics and Vaccine Development

This session will cover key developmental aspects related to Vaccines & Biologicals. The recent developments in Regulatory & operational environment will be presented.

Moderator:

Kathy Heard
Sanofi Pasteur

Critical Success Factors in Managing Global Clinical Trials on Vaccines
Kathy Heard
Sanofi Pasteur

Specifications of Biological Products
Gautam Maitra
AC Immune SA

The Malaria Vacccine Development Program

9.00 AM-10.30 AM SESSION XII (CONVENTION CENTRE)

Biostatistics

The Clinical trials have been increasingly becoming more complex, newer type of drugs are getting discoverved and developed. Establishing efficacy and safety has become a challenge to stake holders of drug development professionals and regulatory bodies, more so for statistical fraternity. Further there is growing emphasis on cutting down the duration of trial, using fewer patients and making clinical trial process more efficient. In this session, experts from statistical field will try to share their experiences on topics of current interest.

Moderator:

Suresh Bowalekar
Pharmanet, India

Adaptive Designs - Regulator's Viewpoint
William Sietsema
University of Cincinnati, USA

FDA/CDER Office of Biostatistics: Guidance Documents for Industry and Science Needs
Ram Tiwari
Office of Biostatistics FDA

Statistical Consideration in Discovery and Evaluation of Biomarkers for Clinical Use
Viswanath Devanarayan
Exploratory Statistics, Abbott Laboratories

10.30-11.00 AM REFRESHMENT BREAK/ EXHIBITOR VISIT

CONCURRENT SESSIONS

11.00 AM-12.30 PM SESSION XIII (GRAND BALLROOM)

Clinical Trial Supplies / Logistics Management — Challenges and Issues of Clinical Trial Logistics from Global and Indian Prespective

India is now increasing becoming one of the major centres within the global clinical trial market with its involvement set to increase sharply in next 3-5 years. The country undoubtedly offers great advantages in terms of cost, patient pools and clinical expertise – but to take advantage of what India's has to offer, you require clinical trial logistics (clinical Supply chain, central testing lab, etc) that are fully adapted to the unique challenges posed in operating in India.

Moderator:

Brigitte Franke-Bray
DIA European Office

Recent Trends in Central Laboratory Services
Palat K Menon
Quest Diagnostics India Pvt. Ltd.

Clinical Trials Supplies Emerging Trends and Opportunities
Sean Smith
Thermo Fisher Scientific

Cold Chain Management
Vinod Jonathan
World Courier India Pvt. Ltd.

11.00 AM-12.30 PM SESSION XIV (CONVENTION CENTRE)

Data Management

The Clinical Data Management (CDM) process, in the drug development business, is becoming more and more IT driven. Its role in the management of clinical trials is still evolving with the emerging technology. It is well known that major part of the success of any clinical trial project lies in how robust are the processes and infrastructure of CDM facility.

The Computer Systems or Software which allow Data capture, Data cleaning, Data reporting, Data extraction and data storage in a back-end Database are called Clinical Data Management systems (CDMS).

The expert speakers in this session will discuss this most IT driven process with emphasis on today and tomorrow.

Moderator:

Bala Sankarnarayanan
Cognizant, India

Growing Role of Data and Data Management in the evolution of Clinical Trial Processes
Graham Bunn
Medidata Solutions

Adaptive Clinical Trials - Opportunities and Challenges for India
Gunjan Jain
Oracle, India

Safety Data Management: Opportunity and Challenges
Chitra Lele
Sciformix Corp

12.30-1.30 LUNCH BREAK

1.30.3.30 PM SESSION XV (GRAND BALLROOM)

Global Clinical Development and Best Regulator Meeting Practices in the US, EU, Japan, and India

This session will illustrate best practices in industry-regulator communications with regards to global and local clinical development plans and clinical trials. Examples to relate to the US, EU, Japan, and Indian experiences.

Moderator
Alberto Grignolo
PAREXEL Consulting US

How to Conduct Effective Clinical Development Meetings with USFDA
David Mantus
Cubist Pharmaceuticals, USA

The EU Scientific Advice Process: Roadmap for Clinical Development Success
Joseph Scheeren
Bayer Healthcare Pharmaceuticals

DCGI Perspective and Advice on Effective Clincal Trial Consultations with Industry
V G Somani - Invited

Effective Interactions Between Industry and the DCGI Office on Clinical Development
Mamta Sharma
PAREXEL Consulting US

PMDA Perspective on Effective Clinical Trial Consultations with Industry in Japan
Yoshiaki Uyama
PMDA Japan

3.30- 4.00 PM REFRESHMENT BREAK

3.00- 5.00 PM

Career Development in Clinical Research

Career Development in Pharma and IT Healthcare
Archana Jain
Accenture
Vinod Kumar C
Aris Global
Subbaraju Sagi
TechSol
Hufriz Karkaria
Quintiles

4.00 PM-5.00 PM

Valedictory Function

Larisa Nagra Singh
Voisin Consulting Life Sciences
Sultan Ghani
DIA India
Announcement of the 6th Annual DIA Meeting – Theme, Time, Date, and Location

5:00 PM CONFERENCE ADJOURNED

WATCH FOR THE 2011 DIA CALENDAR OF CONFERENCES!

TRAVEL AND HOTEL

The Lalit Ashok is located in plush Kumara Krupa High Grounds, overlooking an 18-hole golf course, with key government offices and commercial centers in close proximity. The newly renovated hotel now has a contemporary and elegant look featuring the very latest in design trends, guest amenities, and services. Besides its fabulous location, the hotel is very well known for its creative dining options and extensive banquet facilities. The hotel is about 35 km away from the new International Airport and 5 km from City Center.

For reservations contact: Hotel Lalit Ashok, Bangalore
Contact Person: Mr. Kabir Ahmed
Tel No: 080-30527777 Fax: +91.9845019341
Email: kahmed@thelalit.com

MEETING CONTACTS

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▶ **DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.**

CANCELLATION POLICY: On or before SEPTEMBER 25, 2010

Cancellations must be in writing and be received by September 25, 2010. Registrants who do not cancel by that date and do not attend 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, the organizers are not responsible for any airfare, hotel or other costs incurred by registrants.

Upon cancellation, the administrative fee that will be withheld from refund amount is:

FULL MEETING CANCELLATION ***(All refunds will be issued in the currency of original payment):***
Member/Nonmember Registration = INR 3,000 • Student Registration = INR 500

PLEASE CONSIDER THIS FORM AN INVOICE

5th Annual Conference on Drug Discovery and Clinical Development

Meeting the Challenges of Next Generation R&D: Enhancing Efficiency, Effectiveness & Innovation

Meeting I.D. # 10659 – October 23-26, 2010 – Hotel The Lalit Ashok, Bangalore, INDIA

Registration Fees *Registration fee includes refreshment breaks and luncheons and will be accepted by mail or fax.*

Join DIA now to qualify to save on future events and to receive all the benefits of membership. To see all the benefits of DIA membership, visit www.diahome.org and click on Membership.

	BASIC RATE	TAXES	TOTAL
Standard Membership	1768	182	❑ INR 1950
Student Membership*	725	75	❑ INR 800

MEMBER

	BASIC RATE	TAXES	TOTAL
Industry	9418	582	❑ INR 10000
Academia	4709	291	❑ INR 5000
Student*	2825	175	❑ INR 3000

NONMEMBER (Inclusive of Membership)

	BASIC RATE	TAXES	TOTAL
Industry	11186	764	❑ INR 11950
Academia	6477	473	❑ INR 6950
Student*	3550	250	❑ INR 3800

TUTORIALS
Industry, Academia, and Students

	Tutorial 1	Tutorial 2	Tutorial 3	Tutorial 4	Tutorial 5	Tutorial 6	Tutorial 7	Tutorial 8
BASIC RATE	2825	2825	2825	2825	2825	2825	2825	2825
TAXES	175	175	175	175	175	175	175	175
TOTAL	❑ 3000	❑ 3000	❑ 3000	❑ 3000	❑ 3000	❑ 3000	❑ 3000	❑ 3000

EXHIBITS

	BASIC RATE	TAXES	TOTAL
Booth	135993	14007	❑ INR 150000
Banner	9066	934	❑ INR 10000

To receive information on a Banner Display, please check this box: ❑

***A limited number of student registrations are available.**
A student is an undergraduate/graduate who can document enrollment in a Signature accredited, degree granting, academic program. Student registration is by fax or mail only. Please send completed registration form, copy of student identification, and payment.

TOTAL AMOUNT DUE: _____

Mail or fax this form to +91-22-28594762.

Please check the applicable category:
❑ Academia ❑ Government ❑ Industry ❑ CRO ❑ Student

PLEASE PRINT ALL INFORMATION CLEARLY

Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Last Name (Family Name)

First Name M.I.

Job Title

Affiliation (Company)

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

Postal Code

City

Country

Telephone Number

Fax Number

email (Required for confirmation)

PAYMENT INFORMATION

❑ DEMAND DRAFT/CHEQUE

Completed form, along with draft/cheque made payable to DIA (India) Private Limited should be sent to:

DIA (India) Private Limited, A-303, Wellington Business Park I
Andheri-Kurla Road, Marol, Andheri (East), Mumbai 400 059 India
Phone: +91-22-6765-3226 Fax: +91-22-28594762

IF FAXING OR MAILING THIS FORM, PLEASE PROVIDE A COPY OF YOUR BUSINESS CARD.