Clincal Data Management 2010

19, October 2010, ITC Maratha, Mumbai, India

"Creating an optimised data integration & standardised data collection for a secured future for CDM"

Key Speakers Include:

Dinesh Pillaipakkamnatt, Global Head - DB Programming, IIS TS, **Novartis**

Celestine Juliet, Project Manager, Regulatory Affairs, Clinical Research, **Cipla**

Chirag Trivedi, Head - Medical Affaris Clinical Operations, **Sanofi Aventis**

Shamjith Das CK, Head of Clinical Data Management, **Veeda Clinical Research**

Poonam Sule, Senior Clinical Study Manager, **Pfizer**

Anil Arekar, Senior Consultant – Biostatistics - Asia Pacific, **Johnson & Johnson**

Deepti Sanghavi, Medical Advisor- Clinical Research, **Wockhardt**

Milind Antani, Head-Pharma LifeSciences group, **Nishith Desai Associates**

Zinobia Madan, Founder & Managing Director, **ClinOma Healthcare**

Milind Sardesai, Medical & Regulatory Affairs, Clinical Research Physician, **Chiltern**

Prashant Bodhe, Head Regulatory Affairs & VP Operations, **DMRI** (Former Head Regulatory Affairs, **Cipla**)

Jino Joseph, Senior SAS Programmer, **GlaxoSmithKline**

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CONFERENCE INTRODUCTION:-

The pharmaceutical business is under huge pressure and needs to be more competitive if it is going to stay successful. Every day companies generate large amounts of data, much of which is never fully leveraged. Traditional approaches to data collection and management prevent the full curation of all data within a company, leading to a substantial opportunity lost for that company. Why is this? Do companies really understand the full power of the data they own? What can be done by your members of your organisation to advance the thinking and technology?

India has developed into a super power for IT skills and has become a major hub for pharmaceutical and biotech manufacturing and contract research, the outsourcing business in various other segments is also exhibiting promise. Clinical trial data management and statistical analysis is one such area which is growing rapidly, accompanied by a variety of players entering into different models of this business. This conference will reflect on the data management business in India and review the emerging outsourcing models in this growing pharma industry.

Few tasks in R&D rival the complexity of clinical data management while its importance in providing clean and correctly mapped data carries direct impact on the success of drug submission. In times of increasing trial costs and the rising threat of clinical outsourcing, keeping ahead of competition and abreast of the latest developments is paramount to surviving a harsh CDM climate. The role of data managers has experienced a fundamental shift from doer to controller, from data collector to system administrator. This year's conference will capture the essence of electronic data integration, interface interoperability and system optimisation to spearhead a global understanding of data standardisation and usher clinical data management into a time- and cost-efficient second generation. Meticulous care has been taken to offer practical solutions and real-life case studies to combat the challenges of CDM. Market leaders will share their ideas and outline their action plan to crucially assist your decision-making process when improving Data capture and integration, Outsourcing strategies, Data cleaning, validation and mapping, CDISC implementation and compliance, Vendor and project management skills

CDM 2010 will provide you with the data that you need to recognize this complex and rapidly-expanding sector. Knowing the future market, and what impact will that have on future business opportunities? This is your opportunity to stay ahead by learning the latest trends and networking with the trend setters.

It gives us immense pleasure in welcoming you to the Clinical Data Management '2010.

Key themes discussed at this Summit:

- **Current trends of clinical data management & how can you take advantage of the current global market**
- **Driving for success is highly vital, but are you driving as smart as with strategies and tips on the most efficient ways to register clinical trials and results while best utilizing available resources**
- **Data management, CMC SCM, operational requirements & CRO infrastructure in India & South Asia**
- **Discovering cutting edge EDC technology and assess the latest database and data capture systems available**
- **Leverage the importance of CDISC compliance and standardized data capture to achieve effortless submission**
- **Overview of the various types of data that data managers working in oncology handle and the associated challenges**
- **How to land up in finding the right BPO partner**
- **Achieving consistent application & implementation of data standards to speed trial process**
- **Identifying the key critical factors for developing knowledge and skills in vendor management**
- **Attain solid vendor management skills to expertly juggle outsourced tasks**
- **Discovering technologies and strategies for successful clinical data management**
- **Avoiding potential pitfalls of data management**
- **Working with limited budget to ensure on time study completion**
- **Be prepared for audits; site, CRO and in-process trial audits**

Why should you attend:

Clinical Data Management 2010 - "Creating an optimised data integration & standardised data collection for a secured future for CDM"

Get more from the event, with a **broader scope bringing the whole communications value chain together**. Enjoy and make the best out of our **dedicated networking drinks time**, **meet the leading international vendors** showcasing the technology of tomorrow in the co-located exhibition. **Expand your knowledge** of the latest business models and technologies in the high-level conference.strategies in the high-level conference.

Target Audience:

The audience will be made up of Vice Presidents, Directors and Managers within pharmaceutical and biotech manufacturers from the following areas:

Data Management, Outsourcing, Clinical Operations, External Alliances, Clinical Trials, Clinical Research, R&D, Project Management, Contracts, Legal Counsel, Data Management, Clinical Operations, Electronic Data Capture,Clinical Trials, Clinical IT, Biostatistics, E-Clinical Management, Database Services, Clinical Research, Regulatory Affairs & Quality Assurance

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19th October 2010

08:30 – Coffee and registration

09:30 – Chair's opening remarks

Zinobia Madan, Founder & Managing Director, ClinOma Healthcare

09:40 – Examining the current status and future prospects of bioinformatics & data management in India

- Clinical data management in 2010 and beyond: India as a leader
- How can you take advantage of the global market for CDM?
- Emerging technologies that can be deployed to generate revenue
- How can you take advantage of the global market for clinical trials?
- What will data management look like in 2015? What can we do to prepare?

10:20 – Driving Data Management – the Cost, Future and Unknown

- Driving success with highly effective project management
- Driving success with highly effective EDC
- Using CDISC ODM to deliver proven time and cost savings in study set-up

11:00 – Morning coffee & Discussion

11:20 – Selecting the optimal EDC provider to receive quality data

- Exploring the crucial criteria for EDC providers to boost your ability to meet your specific business needs
- Assessing the specific technical advantages of newly available EDC platforms to choose the right equipment for your company
- Gaining a global perspective on how to effortlessly and cheaply implement e-processes in the e-world
- Best way to implement EDC in to speed up the process & achieve full machine executability in database reading
- Using eClinical tools to improve data quality

Dinesh Pillaipakkamnatt, Global Head - DB Programming, IIS TS, Novartis
(http://in.linkedin.com/in/dineshpillaipakkamnatt)

12:00 – Panel Discussion: Evaluating key emerging markets for improved strategy

- Analysing data standards in clinical research: Challenges and future directions
- Successful budget development & analysis - How do sponsors develop study budgets? How do sites price their services?
- Integrating multiple technologies in data management
- Project management in preparation of clinical study reports
- Managing site data and visit tracking
- Screening data for Missing Values and Outliers (Missing values: No uniform guidelines)

Moderator –

Zinobia Madan, Founder & Managing Director, ClinOma Healthcare

Panelists –

Shamjith Das CK, Head of Clinical Data Management, Veeda Clinical Research (http://in.linkedin.com/in/shamjith)

Anil Arekar, Senior Consultant – Biostatistics - Asia Pacific, Johnson & Johnson (http://in.linkedin.com/in/anilarekar)

Deepti Sanghavi, Medical Advisor- Clinical Research, Wockhardt
(http://in.linkedin.com/pub/dr-deepti-sanghavi/5/591/b76)

Poonam Sule, Senior Clinical Study Manager, Pfizer
(http://in.linkedin.com/pub/dr-poonam-sule/7/169/3a6)

12:40 - Networking Luncheon- Take your discussions further & build new relationships in a relaxed & informal setting...

13:30 – Trial Design Considerations

- Analysing the FDA Draft Guidance on adaptive designs for Industry- Feb., 2010
- An Overview of the Guidance on Adaptive Design Clinical Trials for drugs
- An Overview of the Guidance on Adaptive Design Clinical Trials for biologics

Anil Arekar, Senior Consultant – Biostatistics - Asia Pacific, Johnson & Johnson (http://in.linkedin.com/in/anilarekar)

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14:10 – Impact of advanced technology in today's clinical world

- Enable more reliable, smaller, faster, safer trials
- Benefits of Information Technology in clinical trials - (EDC), (CTMS), (CDMS), (DBMS)
- Overcoming issues related with managing security, confidentiality and ethical concerns

14:50 – 'Clinical Operations and Data Management - Together we deliver a Good Quality Trial Faster'.

- What are the common challenges that we face that for both the teams when we interact with each other?
- How Clinical Operations can be an effective partner to Data management at various stages of the study
- Dos and Don'ts for the Clinical Operations Team to help the DM team

Chirag Trivedi, Head - Medical Affaris Clinical Operations, Sanofi Aventis
(http://in.linkedin.com/pub/dr-chirag-trivedi/21/b0/344)

15:20 – Afternoon tea

15:40 – Panel Discussion: Overcoming regulatory challenges in Asian clinical data management - Now and Future

- Introducing recent developments in regulatory affairs and legal challenges for clinical data management
- How to best manage the laws and staying informed on mandates
- Government incentives for Clinical data management in India
- Overcoming challenges faced with differing requirements and regulations in the various host countries
- Successfully complying and staying current with CTRI

Moderator –

Milind Antani, Head-Pharma LifeSciences group, Nishith Desai Associates
(http://in.linkedin.com/pub/dr-milind-antani/3/792/22b)

Panelists –

Milind Sardesai, Medical & Regulatory Affairs, Clinical Research Physician, Chiltern
(http://in.linkedin.com/in/drmilindsardesai)

Prashant Bodhe, Head Regulatory Affairs & VP Operations, DMRI (Former Head Regulatory Affairs, Cipla)
(http://in.linkedin.com/pub/dr-prashant-bodhe/6/b88/2a5)

16:20 – Managing external vendors from a sponsor perspective

- In depth vendor assessment
- Choosing a CDM system that is right for your company
- Role of CDL in the clinical trial process
- Quality control and quality assurance in data management

Celestine Juliet, Project Manager, Regulatory Affairs, Clinical Research, Cipla

17:00 – Pharmaceutical Programming: From CRFs to Tables, Listings and Graphs, a process overview with real world examples

- Clinical Trials Analysis and Reporting process flow
- A bird's eye view of the Analysis considerations as per SAP/RAP
- Overview of TLF programming with industry specific examples
- Stringent QC procedures

Jino Joseph, Senior SAS Programmer, GlaxoSmithKline
(http://in.linkedin.com/pub/jino-joseph/20/586/550)

17:30 - Chairperson's closing remarks and end of conference

Zinobia Madan, Founder & Managing Director, ClinOma Healthcare

17:40 - Networking Drinks - Take your discussions further & build new relationships in a relaxed & informal setting...