



Indian Society for Clinical Research Presents

A Clinical Research Workshop with focus on Efficiencies and Advancements in Clinical Data Management (CDM)

Hotel Daspalla, Jubilee Hills, Hyderabad, Telangana, India

26-27 Oct 2018

Highlights: Time, Cost and Quality are buzz words in Clinical Development arena today. Clinical Data submitted to Regulatory Agencies must meet high quality, scientific standards and be compliant with the regulatory requirements. This two-day workshop is designed to enable the participants to gain more insights on gaining efficiencies in Clinical Data Management and changing landscape in Clinical Trial Development. Participants will be guided through discussions and hands-on exercises to well absorb the learnings. In this workshop, the faculty members will cover the following aspects: Regulatory framework, Database Design and Metadata, Instream Data Cleaning, Impact of DB Unlocks, WHODD Clinical Coding Dictionary, Innovative Trial Designs, Changing landscape through Digital Technologies, RBM in Clinical Research and a panel discussion on future of CDM.

The workshop also includes a half-a-day session exclusive to students, wherein the experts in the field will introduce them to Drug Discovery and Clinical Development, provide an overview on Clinical Data Management and associated career opportunities.

Who Should Attend: Clinical Data Managers, Clinical Data Coders, Clinical Database Programmers and other professionals working with Pharmaceutical Industry or Contract Research Organizations, Research Scholars or Scientists interested in Clinical Research, HealthCare Professionals from Government Agencies, Non-profit Organizations/Associations and Academia, Medicine, Pharmacy, Statistics or Life-sciences Students or Professionals interested in Clinical Research.

Workshop Speakers: Novartis, Pfizer, GSK, PAREXEL, IQVIA, Covance, Syneos Health, TCS, Pharm Olam, Oracle, etc.

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Scientific Committee:

Sebastian Varghese (PAREXEL) - Chair
Sri Vithala (Novartis)
Sachin Tonapi (IQVIA)

Local Organizing Committee:

Sebastian Varghese (PAREXEL)
Sri Vithala (Novartis)
Sandeep Kaswan (PAREXEL)
Vaibhav Jain (GSK)

Agenda

| Day 1: 26-Oct-2018 | | |
|---------------------|---|---|
| Time | Topic | Speaker |
| 8:30 AM – 9:30 AM | Registration | |
| 9:30 AM – 9:40 AM | Welcome | |
| 9:40 AM – 9:50 AM | ISCR orientation | Vaibhav Jain GSK |
| 9:50 AM – 10:00 AM | Introduction to the Program | Sebastian Varghese PAREXEL |
| 10:00 AM – 10:45 AM | Clinical Data Management – Regulatory Framework <ul style="list-style-type: none"> • ICH GCP Guidelines • 21 CFR Part 11 • GCDMP • HIPAA <p><i>Format: Presentation</i></p> | Vani Tulasi Novartis |
| 10:45 AM – 11:15 AM | Tea | |
| 11:15 AM – 1:00 PM | Database design - Metadata Repositories (MDR) <ul style="list-style-type: none"> • Challenges & Risks with Database Design • Protocol Elements • MDR-driven Data Collection • MDR-driven Data Analysis & Reporting • Benefits <p><i>Format: Presentation, exercise & discussion</i></p> | Swatin Shetty & Rupesh Shinde PAREXEL |
| 1:00 PM – 1:45 PM | Lunch | |
| 1:45 PM – 3:15 PM | Instream Data Cleaning – De-risking Data Delivery Issues <ul style="list-style-type: none"> • Improving Data Cleaning Cycle time • Strategies to adopt • Tools to Support • Patient profiling <p><i>Format: Presentation & discussion</i></p> | Sathyavathy Ramanathan & Deepthi Ram Covance |

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|--------------------|---|---|
| 3:15 PM – 4:00 PM | DB Unlocks – Clinical Trial Derailment <ul style="list-style-type: none"> • Root Causes and Risks • Impact of DB Unlocks • Avoiding DB Unlocks <i>Format: Presentation & discussion</i> | Rukmini Kethireddypally PAREXEL |
| 4:00 PM to 4:15 PM | Tea | |
| 4:15 PM to 5:00 PM | Clinical Data Coding – WHODD B3 Format <ul style="list-style-type: none"> • Why WHODD B3 format? • Impact on Data Management • Next Steps <i>Format: Presentation & discussion</i> | Prasanth John Pharm-Olam International |
| 5:00 PM to 5:15 PM | Wrap Up Day 1 | |

Day 2: 27-Oct-2018

| Time | Topic | Speaker |
|---------------------|--|--|
| 8:30 AM – 9:30 AM | Registration | |
| 9:30 AM – 10:15 AM | Innovative Trial Design Models <ul style="list-style-type: none"> • Why Do We Need New Trial Designs? • Direct-to-Patient Clinical Trials • Baskets and Umbrellas Trials • Open Discussion <i>Format: Presentation & discussion</i> | Sri Vithala Novartis |
| 10:15 AM – 11:00 AM | Risk-Based Monitoring (RBM) <ul style="list-style-type: none"> • What's RBM • Is RBM a better solution? • Role of a Data Manager in RBM <i>Format: Presentation & discussion</i> | Suresh Tupakula, Madhurima Gurram, Aanchal Asthana Syneos Health |
| 11:00 AM – 11:15 AM | Tea | |
| 11:15 AM – 12:00 PM | Digital Technology in Clinical Trials <ul style="list-style-type: none"> • e-consents, ePRO and wearables • Data Privacy • Advantages and Challenges <i>Format: Presentation, exercise & discussion</i> | Priyadharsini Parameswaran Pfizer |

| | | |
|--|--|--|
| 12:00 PM – 1:00 PM | Panel Discussion on Future of Clinical Data Management | Apalla Venkataprabhakar (Novartis) Raghavendra Kalmadi (IQVIA) Jayathirtha Gopalkrishna (Oracle) Sathyavathy Ramanathan (Covance) |
| 1:00 PM – 1:15 PM | Wrap up and Conclusion | |
| 1:15 PM – 2:30 PM | Lunch and Networking | |
| Career Sessions for Students and Freshers | | |
| 2:00 PM – 2:30 PM | Student registration | |
| 2:30 PM – 3:15 PM | Overview on Drug Discovery and Clinical Development | Ritesh Tiwari TATA Consultancy Services |
| 3:15 PM – 4:00 PM | Making a Career in Clinical Data Management (CDM) <ul style="list-style-type: none"> • Competencies and skillsets required • Career opportunities | Sebastian Varghese PAREXEL |
| 4:00 PM – 4:30 PM | Tea and Networking | |
| 4.30 PM – 5:15 PM | Meet the experts – Q&A with the students | Novartis, Pfizer, GSK, PAREXEL, IQVIA, Covance, Syneos Health, Oracle, etc. |
| 5:15 PM – 5:45 PM | Wrap Up and Certificate Distribution | |

| ISCR SPONSORSHIP CATEGORIES* | | | | |
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| Sponsorship Offerings | Platinum Sponsor Rs. 50,000 | Gold Sponsor Rs. 25,000 | Silver Sponsor Rs. 15,000 | Sponsor for Kit-Bag Rs. 50,000 |
| Complimentary Table / Booth Space at Venue | Yes (Medium) | Yes (Medium) | Yes (Small) | Yes (Medium) |
| Free Delegate Registration | Four | Three | Two | Four |
| Logo on Flyer | Yes | Yes | Yes | Yes |
| Logo on Standees/Banner | Yes | Yes | Yes | Yes |
| Logo on Delegate Kit | No | No | No | Yes |

*ISCR is the sole sponsor of this event

| Delegate Fees (Full workshop) | | Registrations by 05 Oct 2018 | Registrations after 20 Oct 2018 |
|---|-----------------------|------------------------------|---------------------------------|
| | Academia | | Rs 2500/- |
| ISCR Member | | Rs 3500/- | Rs 4000/- |
| Non ISCR Member | | Rs 4500/- | Rs 5000/- |
| Delegate Fees (Career Session only on Day 2) | Students and Freshers | Rs 400/- | Rs 500/- |

Online Registration: <http://www.iscr.org/events-registration/>

Online Payment: <http://www.iscr.org/payment-events-workshops/>

Group Registrations: For group registrations, 1 is free with 5 registrations (pay for 4, additional 1 is free)

Offline Payment: Cheque/DD payable at Mumbai should be made in favor of "Indian Society for Clinical Research" & mailed to us a

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