DIA Risk-based Monitoring Conference

Demystifying Risk-based Monitoring

Hear TransCelerate's Views on Risk-based Monitoring

ID# 14651 | May 23-24, 2014 | Scitech Center | Mumbai, India

For more information visit **diahome.org/India-RBM**

PROGRAM COMMITTEE

Chirag Trivedi
Director, Clinical Study Unit
Sanofi

Jagadeesh Rudraswamynath
Senior Director, Centralized Data and Operational Surveillance
Quintiles

Rajesh Jain
Director Operations
Cognizant Business Process Services

Suresh Ramu
CEO
Cytespace

KEYNOTE SPEAKER

Syed Shah
Global Head, Strategic Planning & Operations
Global Clinical Operations
Novartis Pharma AG

PROGRAM CHAIR AND KEYNOTE SPEAKER

Nimita Limaye
Vice President
Medical Writing Risk-based Monitoring and CDM, TCS

SPEAKERS

Ashwini Mathur
Head Global Clinical Operations India
Novartis

Y. K. Gupta
Professor & Head, Department of Pharmacology
AIIMS

Yashesh Mehta
Senior Director
Process Excellence
CyteSpace

Anita Limaye
Director
Process Delivery
Quintiles

Chirag Trivedi
Director
Clinical Study Unit
Sanofi

SESSION CHAIRS

Ashwini Mathur
Head Global Clinical Operations India
Novartis

Nimita Limaye
Vice President
Medical Writing Risk-based Monitoring and CDM, TCS

Chirag Trivedi
Director
Clinical Study Unit
Sanofi

Dinesh Pillaipakkamnat
Global Head, Central Analytics Function
Novartis

Gunjan Jain
Principal Solutions Consultant, South Asia
Oracle Health Sciences

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Hemant Rehani
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Jagadeesh Rudraswamynath
Senior Director
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Khalid Saifuddin
Head, Global Central Monitoring (GCM)
Global Clinical Operations (GCO-COS), Novartis Healthcare Private Limited

Jinu Idiculla Jose
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Rajkumar Sinha
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Shabana Khan
Manager, Feasibility & Market Access Services
Ecron Acunova

Nitin Kumar
Head, Technology Excellence Group
Life Sciences
TCS

Suresh Ramu
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Subashri Shivkumar
Hub Unit Director, Regional Clinical Operations
Bristol Myers Squibb

Sumit Goyal
Director
Clinical Research India, Inventiv International Pharma Services Private Limited

Tapankumar M. Shah
Trial Clinical Monitor
Boehringer Ingelheim India Private Limited

Veerabhadra S. Nayak
Global Lead CRA (Global Clinical Operation)
RPG Strategic Solutions

WHO SHOULD ATTEND

Senior professionals driving Risk-based Monitoring initiatives within their organization, including those from:

- Clinical Strategy
- Business Operations
- Clinical Operations
- Clinical Data Management
- Biostatistics
- Analytics
- IT and Technology
- Quality
- All clinical research professionals such as data managers, clinical research associates, site coordinators and others from the clinical space who wish to get inducted to Risk-based Monitoring
- Global players looking at setting up Risk-based Monitoring operations in India should also attend this event

PROGRAM OVERVIEW

Risk-based Monitoring (RBM) is a niche area that is transforming the clinical trial industry. RBM involves an orchestrated interplay between core clinical domain, data management, biostatistics, analytics, quality and regulatory, and of course the sites as well, and this program will touch upon all of these components.

It will delve into risk assessment, the RACT tool, the monitoring plan and the complexities involved in defining risk indicators, the evolving roles of the key stakeholders, the governance, implementation challenges, industry and regulatory perspectives, and how India can be a key player in this space.

The need of the pharma/biotech industry is to drive a leaner approach to drug development, while emphasizing patient safety. This conference will highlight how RBM will be a key enabler for this.

FEATURED TOPICS

- RBM – regulatory guidances and industry perspectives, benefits, and challenges
- Integrating Quality – QBD, the RACT tool – ensuring patient safety
- Defining and managing risk at different levels – risk indicators
- Strategies for developing the protocol and monitoring plans
- Predictive Analytics
- Roles are changing – CRA/CDM
- Managing the sites – does anything change?
- Technology solutions and vendor evaluation
- Data integration and associated complexities

All attendees will receive a DIA Certificate of Attendance at the conclusion of the event.

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www.diahome.org

Day 1 | Conference Agenda

9:30-10:00 REGISTRATION

10:00-10:30 INAUGURATION

10:30-11:00 KEYNOTE ADDRESS

RBM – Transforming the Clinical Trial Industry

Syed Shah
Global Head Strategic Planning & Operations, Global Clinical Operations
Novartis Pharma AG

Session 1 | Risk-based Monitoring: Evolving Industry Perspectives

Session Chair
Chirag Trivedi
Director, Clinical Study Unit
Sanofi

11:00-11:30 *TransCelerate BioPharma – IQRMP, RACT and QBD*

Representing TransCelerate
Chirag Trivedi
Director, Clinical Study Unit
Sanofi
Subashri Shivkumar
Hub Unit Director, Regional Clinical Operations
Bristol Myers Squibb

11:30-12:00 *RBM and ROW – How do we Drive RBM in Global, Multicentric Trials?*

Sumit Goyal
Director, Clinical Research, India
Inventiv International Pharma Services Private Limited

12:00-12:30 TEA BREAK AND NETWORKING

Session 2 | Technology as the Game Changer for RBM

Session Chair
Nitin Kumar
Head, Technology Excellence Group, Life Sciences
TCS

12:30-1:00 *Selling an RBM Solution — What Should Technology Offer?*

Nitin Kumar
Head, Technology Excellence Group, Life Sciences
TCS

1:00-1:30 *Managing Science while Integrating Technology in RBM*

Rajkumar Sinha
Senior Director, GDSM
Quintiles

1:30-2:30 LUNCH

Session 3 | The Science of RBM

Session Chair
Ashwini Mathur
Head Global Clinical Operations India
Novartis

2:30-3:00 *QBD — Integrating Risk Management at the Protocol Level*

Harshad Kulkarni
TA Statistician and Onsite Program Manager
Cognizant

3:00-3:30 *Risk Indicators and Triggers — Getting them Right: Shifting from SDV to SDR*

Dinesh Pillaipakkamnat
Global Head, Central Analytics Function
Novartis

3:30-4:00 *Analytics and RBM — The Statistics Behind it All!*

Ashwini Mathur
Head Global Clinical Operations India
Novartis

4:00-4:45 TEA BREAK AND NETWORKING

Session 4 | Panel Discussion

4:45-5:30 *RBM — Is it About Technology or Science?*

Panel Chair
Suresh Ramu
CEO
Cytespace

Panelists

Ashwini Mathur
Head Global Clinical Operations India
Novartis
Gunjan Jain
Principal Solutions Consultant, South Asia
Oracle Health Sciences
Nitin Kumar
Head, Technology Excellence Group, Life Sciences
TCS

5:30 DAY 1 ADJOURNED

Day 2 | Conference Agenda

9:30-10:30 KEYNOTE ADDRESS

Disruptive Innovation in Clinical Trials and Healthcare

Nimita Limaye
Vice President, Medical Writing
Risk-based Monitoring and CDM
TCS

Session 5 | Change Management in RBM

Session Chair
Hemant Rehani
Deputy Head, India
Quintiles

10:30-11:00 ***The Site's Perspective — Like It or Not!***

Yashesh Mehta
Senior Director, Process Excellence
CyteSpace

11:00-11:30 ***Profiling the Clinical Data Monitor — A New Role in the Making***

Anita Limaye
Director, Process Delivery
Quintiles

11:30-12:00 TEA BREAK AND NETWORKING

Session 6 | Implementing RBM

Session Chair
Khalid Saifuddin
Head, Global Central Monitoring (GCM)
Global Clinical Operations (GCO-COS)
Novartis Healthcare Private Limited

12:00-12:30 ***Challenges and Successes in Managing an Onshore/ Offshore RBM Partnership — The Do's and Don'ts***

Jagadeesh Rudraswamynath
Senior Director, Centralized Data and Operational Surveillance, Quintiles

12:30-1:00 ***Digital Strategy: e-Source, the eICF and e-Monitoring***

Gunjan Jain
Principal Solutions Consultant, South Asia
Oracle Health Sciences

1:00-1:30 ***Defining KPIs for the Successful Implementation of RBM***

Tapankumar M. Shah
Trial Clinical Monitor
Boehringer Ingelheim India Private Limited

1:30-2:30 LUNCH

Session 7 | RBM Strategy

Session Chair
Jagadeesh Rudraswamynath
Senior Director, Centralized Data and Operational Surveillance
Quintiles

2:30-3:00 ***Picking the Right Study and the Right Time to Pilot RBM***

Jinu Idiculla Jose
Director, Asia Process Excellence
Quintiles

3:00-3:30 ***Organizational Health Check: RBM — Are You Ready For It?***

Veerabhadra S. Nayak
Global Lead CRA (Global Clinical Operation)
RPG Strategic Solutions

3:30-4:00 ***RBM: A Steep Climb Ahead — Potential Enablers***

Y. K. Gupta
Professor & Head, Department of Pharmacology
AIIMS

4:00-4:30 TEA BREAK AND NETWORKING

Session 8 | Panel Discussion

4:30-5:15 ***Panel Discussion: The ROI on RBM — Is it Really Worth the Risk?***

Panel Chair
Nimita Limaye
Vice President, Medical Writing
Risk-based Monitoring and CDM
TCS

Panelists

Rajesh Jain
Director Operations
Cognizant
Shabana Khan
Manager, Feasibility & Market Access Services
Ecron Acunova
Sumit Goyal
Director, Clinical Research, India
Inventiv International Pharma Services Private Limited
Y. K. Gupta
Professor & Head, Department of Pharmacology
AIIMS

5:15-5:30 VOTE OF THANKS

Nimita Limaye
Vice President, Medical Writing
Risk-based Monitoring and CDM
TCS

VENUE DETAILS

Scitech Center | Mumbai India
7, Prabhat Nagar, Jogeshwari West, Mumbai. ***Land Mark: Next To Unichem Limited***

CONTACT
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MEETING MANAGER

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CANCELLATION POLICY: On or before MAY 10, 2014

Cancellations must be in writing and received by May 10, 2014. 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.

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.

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*** 75% of the Delegate fee

PLEASE CONSIDER THIS FORM AS AN INVOICE

DIA Risk-based Monitoring Conference: *Demystifying Risk-based Monitoring*

Meeting I.D. # 14651 | May 23-24, 2014 | Scitech Center | Mumbai, India

REGISTRATION FEES

Registration fee includes refreshment breaks, luncheons.

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.

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. Please send completed registration form, copy of student identification, and payment.

Exhibit Rates: 70,000 INR
**One booth attendee and one full conference pass is the part of booth package.

DELEGATE REGISTRATION - MEMBER			
	BASIC RATE	**SERVICE TAX**	**TOTAL**
Industry	8000	989	8989 INR
Academia/Government	3500	433	3933 INR
Student	2000	247	2247 INR
DELEGATE REGISTRATION - NON MEMBER			
Industry	9000	1112	10112 INR
Academia/Government	4000	495	4495 INR
Student	2500	309	2809 INR

TOTAL AMOUNT: _____

ORGANISATION PAN No.: _____

REGISTRATION TERMS AND CONDITIONS: Registration form should be duly filled, signed by the authorized person. You are requested to email the duly filled and signed Registration Form first and then courier/mail it along with registration fees on or before 5 working days of the conference.

PLEASE PRINT ALL INFORMATION CLEARLY

Please check the applicable category:

❑ Academia ❑ Industry ❑ Student

Degrees: ❑ Dr. ❑ Mr. ❑ Ms.

Last Name (Family Name)

First Name

Job Title

Affiliation (Company)

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) **Signatory**

Payment contact person's Full Name Telephone Number email

PAYMENT INFORMATION

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

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