Deciphering the Why, When and How of Risk Based Monitoring

22nd & 23rd September
Mumbai

DIA

PROGRAM CHAIR

Nimita Limaye
CEO
Nymro Clinical Consulting Services

PROGRAM COMMITTEE

Abby Abraham
Vice President
Clinical Solutions
Algorics

Abhijit Parab
Director, CDM
Allergan

Raghu Punnamaraju
Senior Director, Software
Engineering-R&D
Engineering Management
PAREXEL International

Sarvesh Singh
VP and Head APAC - DM
ICON Clinical Research

The latest ICHE6 R2 guidance has driven even the nay-sayers to focus on developing RBM strategies. Without experience and expertise to support the same, one may actually end up adding risk to a study. The industry has an urgent need to understand the strategies involved in RBM, including the development of the IQRMP, the development of a risk scoring model, the identification of the KRIs, the SDV strategy, site-tiering strategy, the road-blocks and the pre-emptive measures, the identification of the proof points and the latest regulations and the tools and technologies involved. In addition, this conference will touch on the role of the risk based monitor and the criticality of a well outlined change management strategy.

Program Highlights

- Key Regulations, Guidances and the industry impact
- Implementation Strategy - When should one ideally implement an RBM model?
- Implementation Methodology – Deploying RBM
- Road Blocks, Pre-emptive measures
- Risk Assessment methodology
- Partnering for RBM – selecting a vendor of choice
- Driving Change – an uphill task

Keynotes

Mubarak Naqvi
Senior Director
Medical & Regulatory Affairs
Sanofi

Seema Pai
Director & Head - India Cluster (India, Philippines & Thailand, Vietnam)
Global Clinical Site Management, Clinical Development & Operations,
Pfizer

MEETING MANAGER

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AGENDA

Day 1 | Friday, 22nd September

8:30 – 10:00 **REGISTRATION**

10:00 – 10:30 **OPENING CEREMONY**

10:30 – 11:00 **KEYNOTE PRESENTATION**

How RBM is disrupting the clinical trial industry – the path ahead
Mubarak Naqvi
Senior Director
Medical & Regulatory Affairs
Sanofi

11:00 – 11:30 Tea / Coffee Break

Session 1

11:30 – 13:00 **Data Driven Monitoring**

Session Chair
Raghu Punnanmaraju
Sr Director - Software Engineering
PAREXEL International

Speakers
11:30 – 12:00
Critical Role of Analytics in Data Driven Monitoring
Soujanya Konda
Team lead for Statistical Programmer
Quartesian

12:00 – 12:30
Risk-Based quality management using the Data driven approach
Sathyavathy Ramanathan
Director - DM
Chiltern

12:30 – 13:00
DDM in Action - Central statistical monitoring and KRI methodologies
Neha Sharma
Manager - RBM
Covance

13:00 – 14:00 LUNCH

SESSION 2

14:00 – 15:00 **Panel Discussion: RBM Implementation Challenges: Vendor Selection, Study Selection, Deployment, Change Management**

Moderator
Nimita Limaye
CEO
Nymro Clinical Consulting Services

Panelists
Veena Jaguste
Clinical Research and Healthcare Consultant
Medicines n We

Abhijit Parab
Director - CDM and Programming
Allergan

Arun Shankar
VP
Chiltern

Annappa Kamath
Senior Portfolio Director
Portfolio Leadership, Phase II/III
PAREXEL International

Ranjeet Gutte
GM- Global Clinical Development
Wockhardt

15:00 – 15:30 Tea / Coffee Break

SESSION 3

15:30 – 16:30 **Evolving Regulations/Guidelines: What do you need to do differently?**

Session Chair
Chandrika Arora
Founder & CEO
QMATRA Services LLP

Speakers
15:30 - 16:00
GCP Goes Risk-Based: a critical review of evolving GCP guidelines and EMA Regulations
Artem Andrianov
CEO
Cyntegrity

16:00 -16:30
RBM, Risk and US Regulations
Lorne Cheeseman
CEO
Kestrel Biologic

16:30 DAY END

Day 2 | Saturday, 23rd Septemeber

9:30 – 10:00 Keynote presentation

RBM: Executive Strategy

Seema Pai
Director & Head - India Cluster
(India, Philippines & Thailand, Vietnam)
Global Clinical Site Management
Clinical Development & Operations
Pfizer

Workshop Part I

10:00 – 11:30 **RBM Implementation Strategy**

Moderator

Sarvesh Singh
VP & Head of APAC - DM
ICON

"Clinical trials have evolved substantially since adoption of ICH E6 GCP in 1996. Increase in globalization, study complexity, and technological capabilities had led to a pressing need for changes in ICH E6 which were done recently. This workshop will cover practical aspects of creating IQRMP, defining KRIs, designing the RACT. You will also get overview of better usage of heat maps and some other visual analytics to help you implement it in your clinical trials. This workshop is designed to be an educational environment where content focuses on actively engaging the topics presented."

11:30 – 12:00 Tea / Coffee Break

Workshop – Part II

12:00 – 13:00 **RBM Implementation Strategy (contd).**

13:00 – 14:00 LUNCH

SESSION 4

14:00 – 15:30 **RBM: The Site, CRO and Pharma Perspective**

Session Chair
Durga Gadgil
Clinical Research Consultant

Speakers
14:00 – 14:30
Establishing Operations in RBM: The CRO Perspective
Prasida Dinesh
Associate Director - CDM
Chiltern

14:30 – 15:00
Allergan RBM Implementation: Strategy: A Case Study
Abhijit Parab
Director - CDM and Programming
Allergan

15:00 – 15:30
The critical role of the CRC in transitioning to an RBM model
Sauren Das
Executive Director
Excel Life Sciences

15:30 – 16:00 Tea / Coffee Break

16:00 – 17:00 **Panel Discussion: Leveraging Technology, Enabling RBM**

Moderator
Abby Abraham
VP - Clinical Solutions
Algorics

Panelists
Rajesh Jain
Co-founder
ConsilX Digital

Pankaj Manon
CTO
Thoughtsphere

Kishore Kumar
Consultant Biostatistician

SharathChandra Paladugu
IT Manager - R&D CADT
PAREXEL International

17:00 – 17:30 Conference Wrap up

Deciphering the Why, When and How of Risk Based Monitoring
Event I.D. 17652 | 22nd & 23rd September, 2017 | Mumbai, India

VENUE:
Courtyard by Marriott Mumbai International Airport
C.T.S No 215 Andheri Kurla Road Andheri East
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CANCELLATION POLICY: ON OR BEFORE SEPTEMBER 11, 2017

- Cancellations must be in writing and received by SEPTEMBER 11, 2017. 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.
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- UPON CANCELLATION, the administrative fee that will be withheld from refund amount is 25 % of the delegate fee

FULL MEETING CANCELLATION

- All refunds will be issued in the currency of the original payment

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A student is an undergraduate/graduate who can document enrollment in a signature accredited, degree granting, academic program. Please send completed registration form, payment and copy of student identification.

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DIA India RBM conference 2017- 22-23, September, Mumbai

Solo Opportunity

Principal Supporter (One)

200000 INR /2941 USD+Taxes

- This is the **'SOLO'** opportunity means only one company can participate as a principal supporter
- Free Booth (Octanorm) Size: 3X2 Meters
- Four (4) full free conference access and two (2) booth attendee passes
- Logo on Registration desk
- Standee at the Entrance Area with company name and logo as a principal supporter(6x3Feet)
- Standee with logo and promotional content at preconference area projecting the company as a Principal Supporter (6x3 Feet)
- Logo panel on Coffee Kiosk
- Reserve seating arrangement for the delegates

Table Top (Two)

100000 INR/1470 USD +Taxes

Table Size:

- 6x2 ½ Feet Skirted Table will be provided by DIA
- You can place your promotional material; Pop Up, Standees or Flyers
- One full complimentary conference access and one booth attendee passes

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