



Webinar

Risk Based Monitoring Application Demo

New Interface & Analytics

Risk Based Monitoring Technology

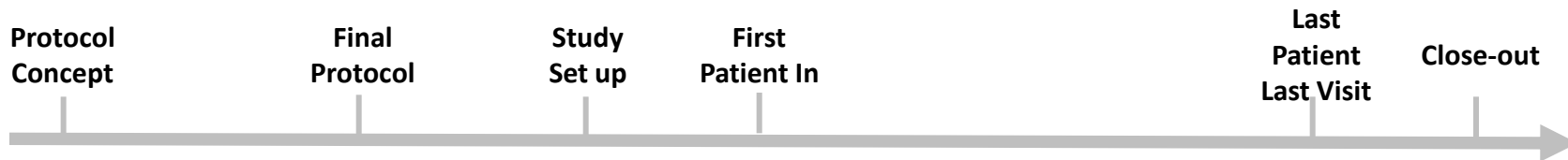


Randy Ramin-Wright

Agenda

- RBM Process
- System Demo
- How to Get Started
- Outlook

- “The sponsor should develop a systematic, prioritized, risk-based approach to monitoring clinical trials...”
- “Selection of sites and/or processes for targeted on-site monitoring.”
- “The sponsor should develop a **monitoring plan** that is tailored to the specific human subject protection and data integrity risks of the trial. “



▶ Study Quality Assessment (SQA)

- Impact on protocol
- Plan critical monitoring & mitigation tasks
- Define monitoring intensity

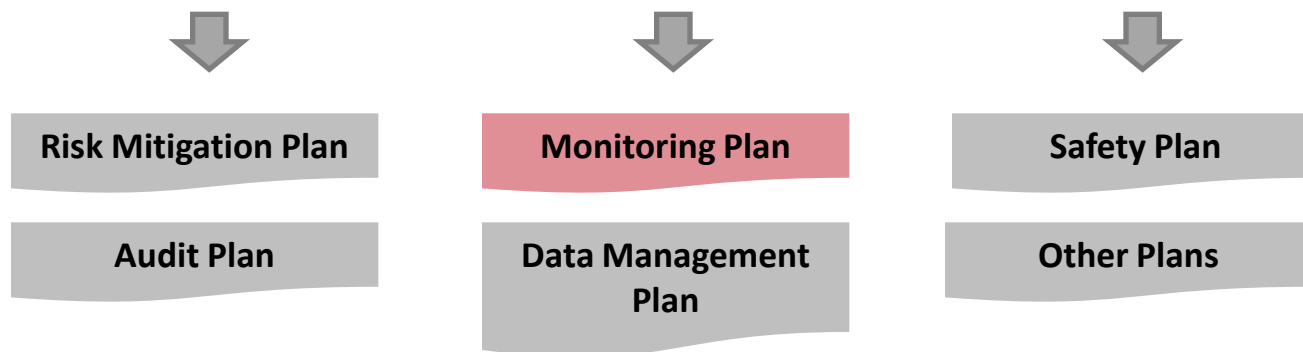
▶ Trial Site Assessment (TSA)

- Impact on site selection

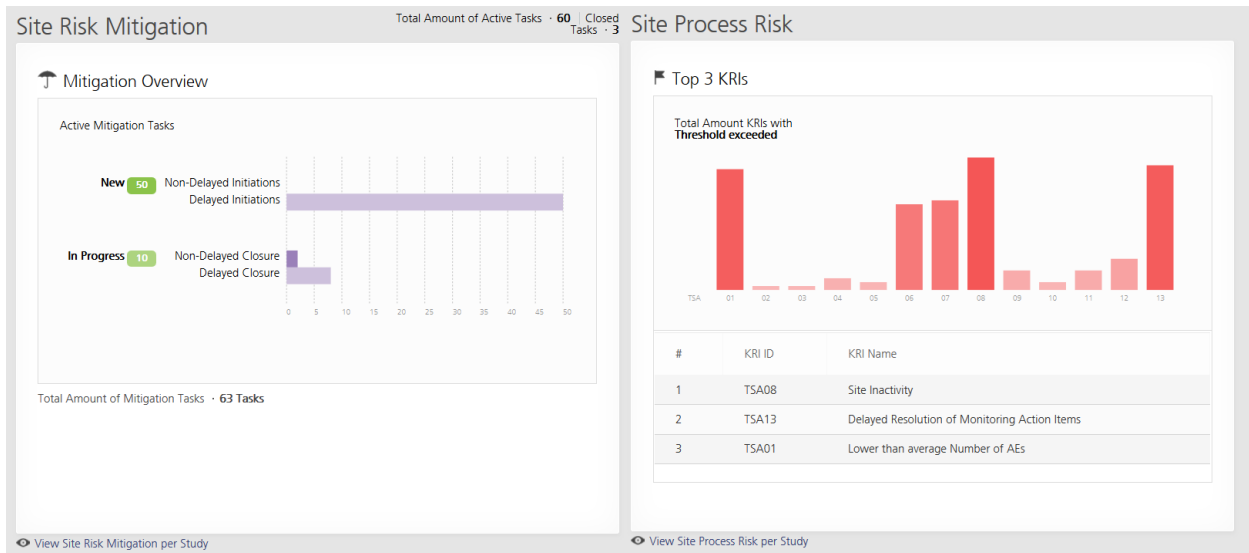
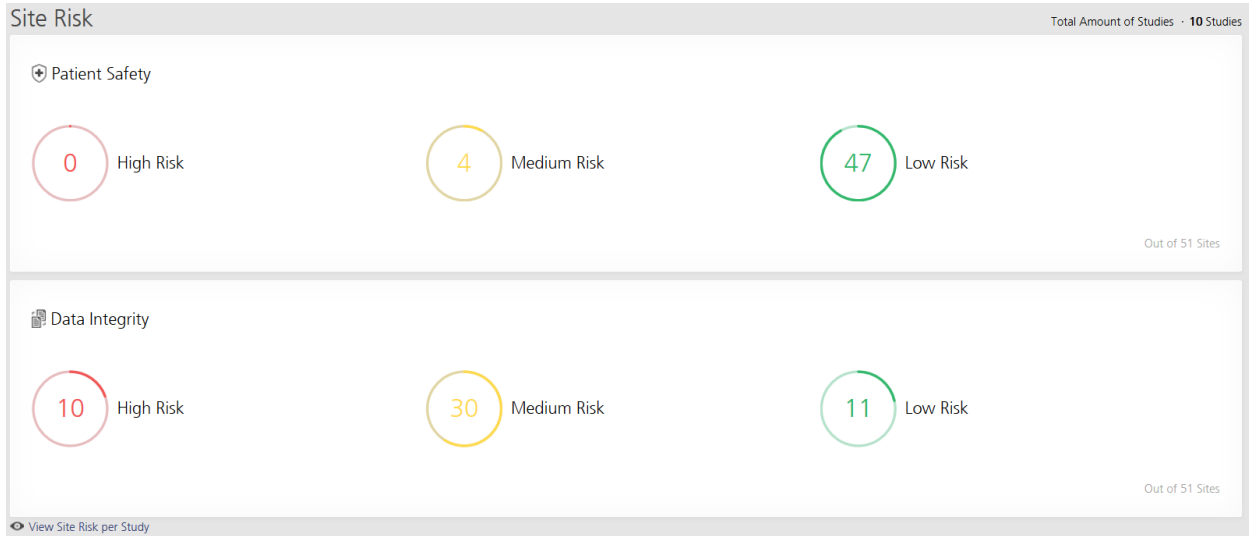
▶ Targeted Monitoring

- Focus on critical areas
- Ongoing risk analysis

▶ Adapt Functional Plans



Integrated Quality Risk Management Plan



Pilot Projects

- Orientation and Planning Workshops
- Setup and configure System
- Train Pilot Project Team
- Pilot Risk-based Approach and Technology
- Gain experience
- Review Results

Make an informed decision about Risk Based Monitoring!

Events:

SCOPE – the Summit for Clinical Ops Executives
on February 23-25, 2016 in Miami FL, USA

HX360, the Executive Forum for health and technology
innovation
February 29-March 3, 2016 in Las Vegas, USA,

Next Webinar:

Demonstration

New Study Quality Risk Analytics User Interface
End of March 2016

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Thank you for attending our Webinar!