

# An Exploration of Risk Based Monitoring from the Site Perspective

## Module 4 of a 4 Part Series



**Nicole Stansbury**  
*Executive Director,  
Adaptive & Intelligent  
Monitoring, PPD*



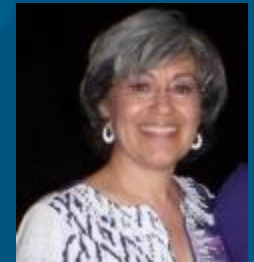
**Emer Doherty**  
*Senior Director,  
Clinical Risk Management  
ICON Clinical Research*



**Crystal Gruetzmacher**  
*Clinical Research Coordinator,  
Black Hills Cardiovascular Research &  
Regional Health Clinical Research*



**Nycole Ramirez**  
*Director,  
Clinical Risk Management  
ICON Clinical Research*



**Melissa Poindexter,  
RN, BSN**  
*President, Advances in  
Health*

# Faculty Disclosure

In compliance with ANCC Guidelines, I hereby declare:

I do not have financial or other relationships with the manufacturer(s) of any commercial service(s) discussed in this educational activity.

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# Poll Question #1

My site has adapted internal processes to accommodate Risk Based Monitoring:

- A. Not at all
- B. A little
- C. Very much

# RBM - focused on the things that Matter



**Error Detection**

**Critical Process and Data**

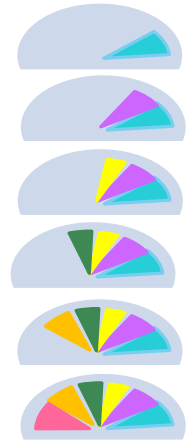
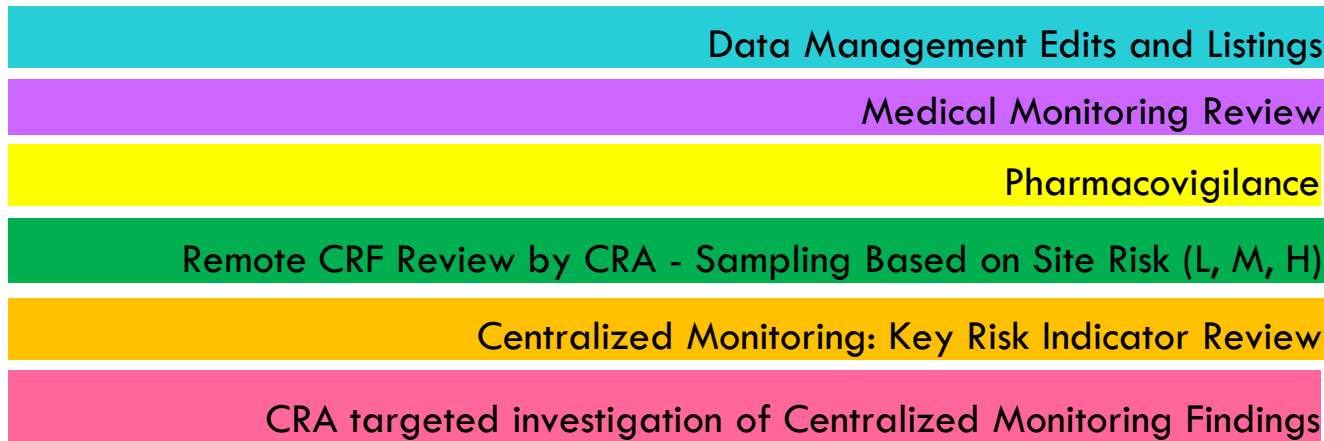
**Patient Safety and Data Reliability**

**Central Key Risk Indicators**

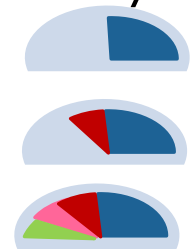
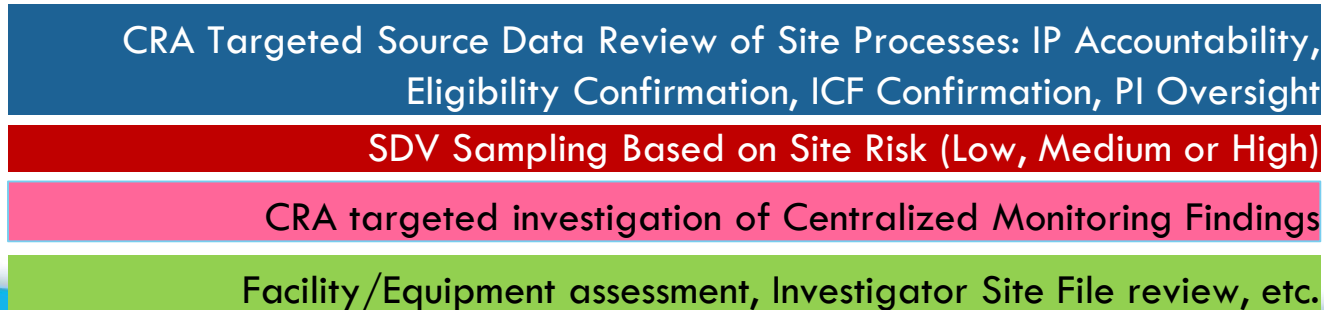


# Multiple Levels of Data Review in RBM

Remote



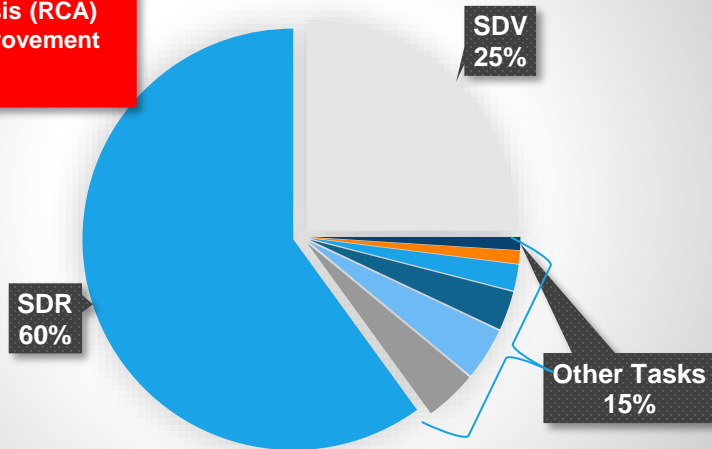
Onsite by CRA



# Reallocation of CRA/On-Site Tasks

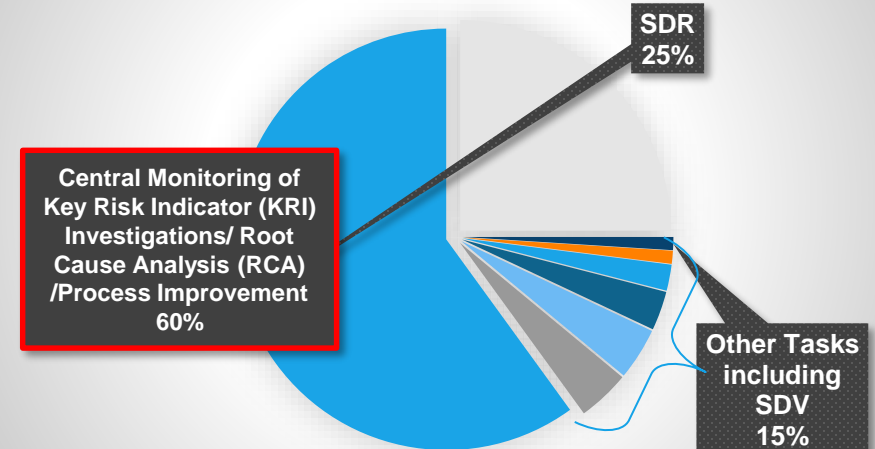
% Time in Traditional MV

Central Monitoring of Key Risk Indicator (KRI) Investigations/ Root Cause Analysis (RCA) /Process Improvement  
0%



% Time in RBM MV

Central Monitoring of Key Risk Indicator (KRI) Investigations/ Root Cause Analysis (RCA) /Process Improvement  
60%



A key risk indicator (**KRI**) is **defined** as a measure that gives an indication of how risky an activity or process or procedure might be.

# Remote Site/CRA Interactions in RBM

Ad Hoc calls as needed

CRA remote visits via telephone to perform targeted tasks:

- investigation of site issues, trends and risks
  - conduct training
- targeted remote EDC logic review (completion/understanding)
  - resolution of outstanding issues
- answer questions/provide clarification
- any other tasks that do not require CRAs to be onsite

Remote



# Proven Benefits of RBM

Focus on what matters = *GREATER PATIENT CENTRICITY*

More timely review of data = *BETTER PATIENT SAFETY*

Fewer critical audit findings = *BETTER QUALITY*

CRA/Site have quality time = *PREVENTION OF ERRORS*





## Poll Question #2

I have a better understanding of remote data review and interactions with CRA in the Risk Based Monitoring model:

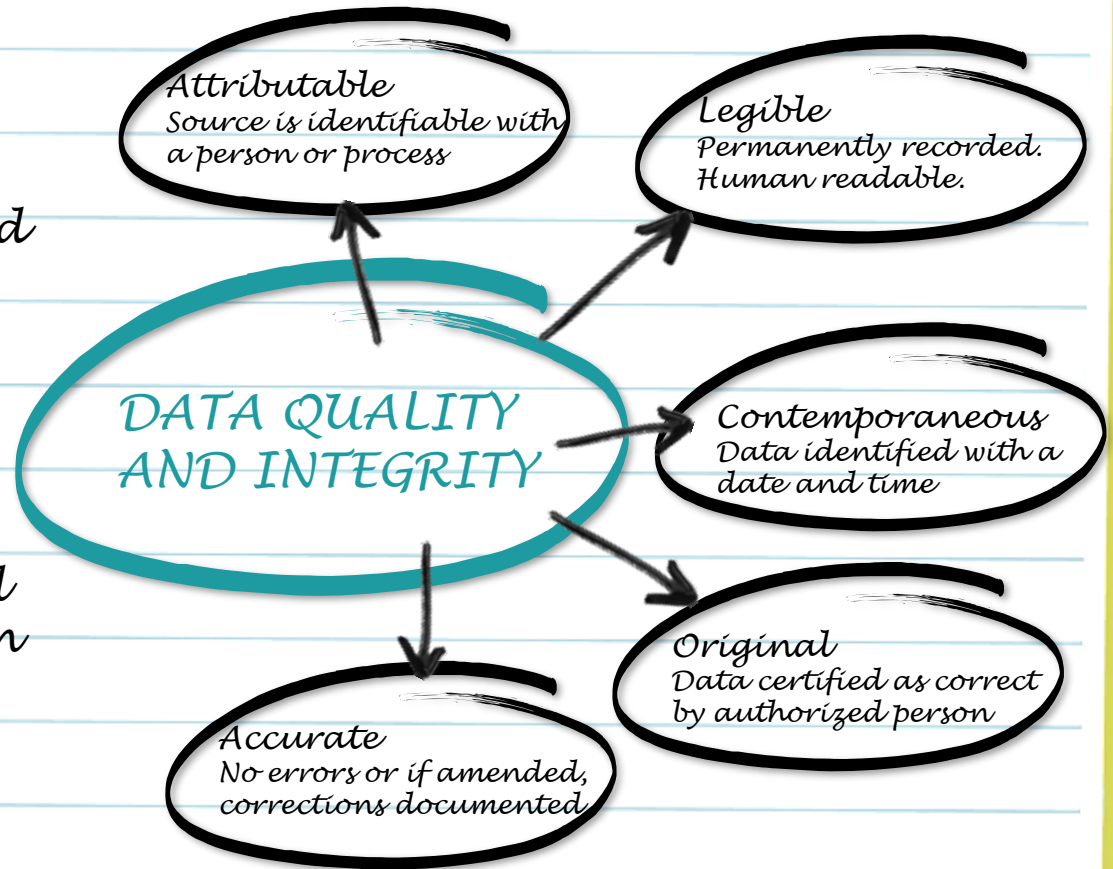
- A. Not at all
- B. A little
- C. Very much

# Common Myths

# Myth 1: “Sites Need to Hire ‘Monitors’ to do the SDV that CRAs are no Longer Doing”

## Site responsibility:

- ✓ Establish clinic procedures designed to maintain accurate subject data and ensure data accuracy.
- ✓ Establish SOPs and/or an internal process to engage in their own QC of data entered into the CRF.



## Myth 2: “Sites work load increases because CRAs are not onsite as often”



# Myth 3: “RBM Requires Faxing/Scanning of Source Documents or Hours on the Phone with CRAs”



## Myth 4: “Sites won’t receive needed support now that the CRA visits are less frequent”

*Out of sight  
but not  
out of mind...*



# Poll Question #3

I have better ideas for making changes at my site to accommodate Risk Based Monitoring :

- A. Not at all
- B. A little
- C. Very much

# Key Takeaways



# Key Takeaways



Still a work in progress

Different companies piloting and exploring different solutions



We are not abandoning you.

We VERY much value your input



# Thank you!

SCRS members can visit  
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