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

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

Emer Doherty
Senior Director, Clinical Risk Management ICON Clinical Research

Nycole Ramirez
Director, Clinical Risk Management ICON Clinical Research

Melissa Poindexter, RN, BSN
President, Advances in Health

1 Society for Clinical Research Sites, Inc. is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center’s Commission on Accreditation.
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.

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
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

Society for Clinical Research Sites, Inc. is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center’s Commission on Accreditation.
## Multiple Levels of Data Review in RBM

<table>
<thead>
<tr>
<th>Onsite by CRA</th>
<th>Remote</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CRA Targeted Source Data Review of Site Processes:</strong> IP Accountability, Eligibility Confirmation, ICF Confirmation, PI Oversight</td>
<td></td>
</tr>
<tr>
<td><strong>SDV Sampling Based on Site Risk (Low, Medium or High)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>CRA targeted investigation of Centralized Monitoring Findings</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Facility/Equipment assessment, Investigator Site File review, etc.</strong></td>
<td></td>
</tr>
</tbody>
</table>

- **Centralized Monitoring: Key Risk Indicator Review**
- **CRA targeted investigation of Centralized Monitoring Findings**
- **Medical Monitoring Review**
- **Pharmacovigilance**
- **Remote CRF Review by CRA - Sampling Based on Site Risk (L, M, H)**
- **Data Management Edits and Listings**
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
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.

DATA QUALITY AND INTEGRITY

- Attributable: Source is identifiable with a person or process
- Legible: Permanently recorded. Human readable.
- Contemporaneous: Data identified with a date and time
- Original: Data certified as correct by authorized person
- Accurate: No errors or if amended, corrections documented
- Legible: Permanently recorded. Human readable.

Accredited Provider
American Nurses Credentialing Center’s Commission on Accreditation
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”
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 [http://myscrs.org/insite/](http://myscrs.org/insite/) to view InSite, the global journal for clinical research sites.