

What's Behind the Curtain? Centralized Monitoring Unveiled *Module 3 of a 4 Part Series*



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What's Behind the Curtain? Centralized Monitoring Unveiled

- Summary:
 - Define what Centralized Monitoring is according to ICH E6 (R2)
 - Current state of Centralized Monitoring
 - Monitoring types to support onsite monitoring
 - Case study
 - Analytics/Technology
 - Future state of Centralized Monitoring/Technology
 - Benefits

Polling question #1

- Do you understand the definition of Centralized Monitoring?
 - a. Yes
 - b. No

ICH Recommends Centralized Monitoring

Centralized monitoring is a remote evaluation of accumulating data, performed in a timely manner, supported by appropriately qualified and trained persons (e.g., data managers, biostatisticians). Centralized monitoring processes provide additional monitoring capabilities that can complement and reduce the extent and/or frequency of on-site monitoring and help distinguish between reliable data and potentially unreliable data. Review, that may include statistical analyses, of accumulating data from centralized monitoring can be used to:

- a) identify missing data, inconsistent data, data outliers, unexpected lack of variability and protocol deviations.
- b) examine data trends such as the range, consistency, and variability of data within and across sites.
- c) evaluate for systematic or significant errors in data collection and reporting at a site or across sites; or potential data manipulation or data integrity problems.
- d) analyze site characteristics and performance metrics.
- e) select sites and/or processes for targeted on-site monitoring.

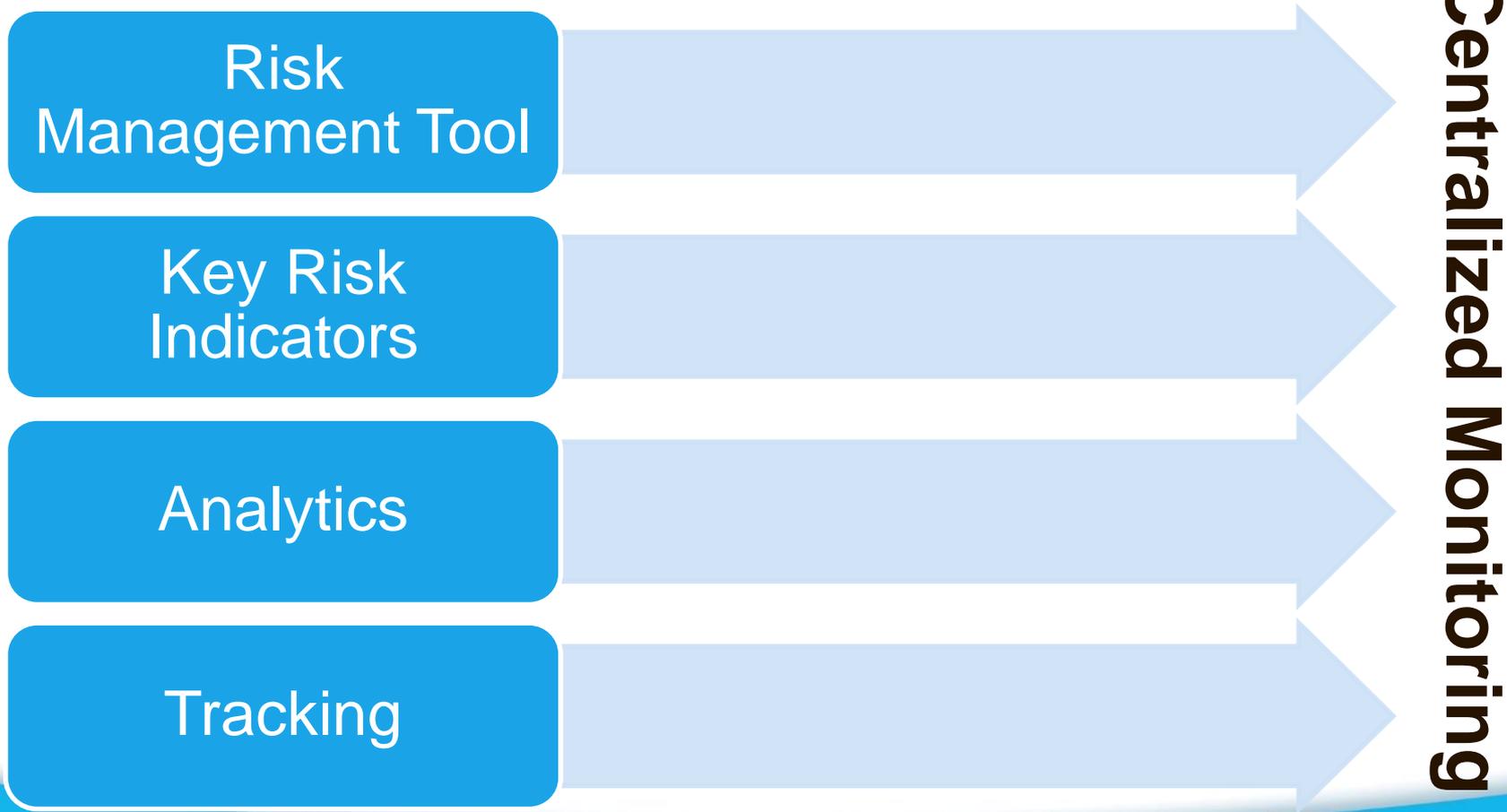
Require reports

Require inclusion in a planning document

How do sites benefit from centralized monitoring?

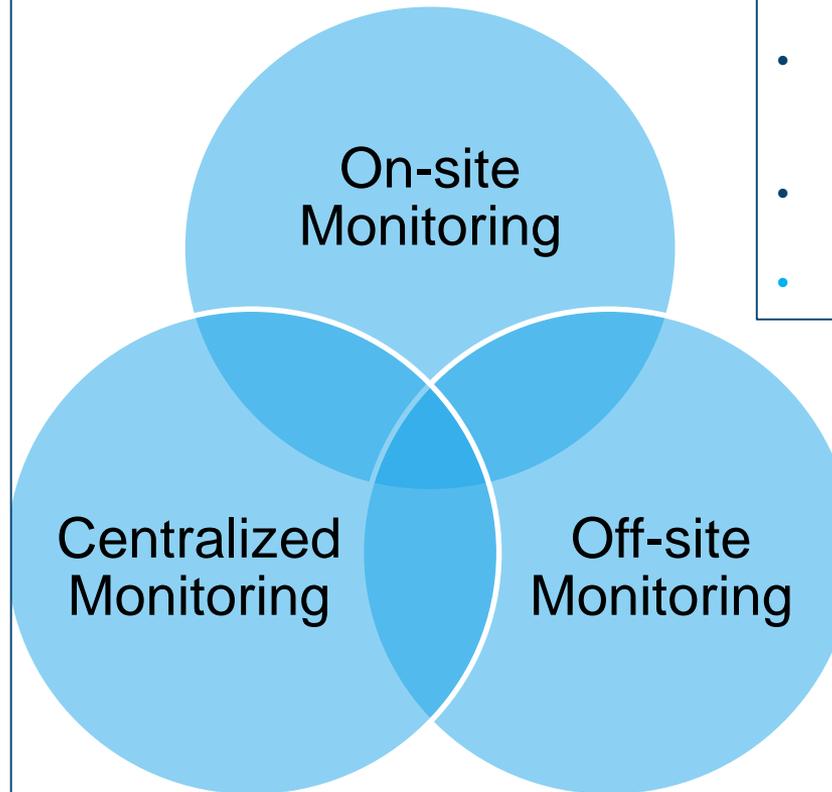
- Faster identification of errors/issues and trends that MATTER!
- Supports CRA's in being able to focus on on-site activities that support the site and drive quality and safety of patients

Technology Supporting Centralized Monitoring Current State



Monitoring Types

- Monitoring data quality and critical data reporting
- Enacting proactive and early identification of quality, safety and operational risks based on the continuous monitoring of data and the risk indicators
- Tracking site performance metrics
- Triggering proposed site contacts and on-site visits based on issues that are identified
- **Data Managers/scientists, statisticians, medical staff, new roles**



- Following up with sites as part of the site management activities
- Performing Source Data Verification (SDV) and Source Data Review (SDR)
- Verifying facility and equipment, and overall quality conduct
- IP and regulatory verification
- **CRAs**

- Coordinating with the sites to manage risks identified during early risk assessment and Centralized monitoring
- Following up with sites as part of the site management activities
- Supporting inquiry management
- Completing various types of data review activities
- **CRAs/in-house CRAs**

Polling question #2

- What is **NOT** a part of Centralized Monitoring?
 - a. Request subject source documentation to be faxed
 - b. Identification of data trends
 - c. Enhanced data quality
 - d. All of the above

The Four A's of Centralized Monitoring

1. Acquire Data
2. Assess Data
3. Analyze Data
4. Action on Data

A Case Study of Centralized Monitoring

A team of central monitors are assigned a group of subjects to follow, throughout the course of the subject's participation in a menopausal study, of an oral investigational drug.

Abbey Brown is a subject participating in the study. A central monitor is analyzing her Visit 6 information posted in EDC by the coordinator, along with the lab results transmitted by the central lab.

While reviewing the subject's vital signs, the central monitor notices a slight increase in her blood pressure, since the last visit and a gradual increase at each visit, since baseline. It is also noted, her liver enzymes are elevated.

While reviewing the data of the other subjects assigned, it is noted the elevations are not unique to Abbey Brown.

Continued...

The central monitor flags the data and sends an alert to the data scientist. As a result of the alert, the data scientist reviews similar data for all study participants, specifically, lab, AEs, and blood pressures and confirms a trend. The medical team is notified of a possible global trend and analyzes the data. The medical team decides to amend the protocol to include safety liver enzymes at each visit and drop subjects whose BPs are > 160/90. In addition, the team decided to add blood pressures and liver enzymes as key data points, to be verified at 100% for all subjects.

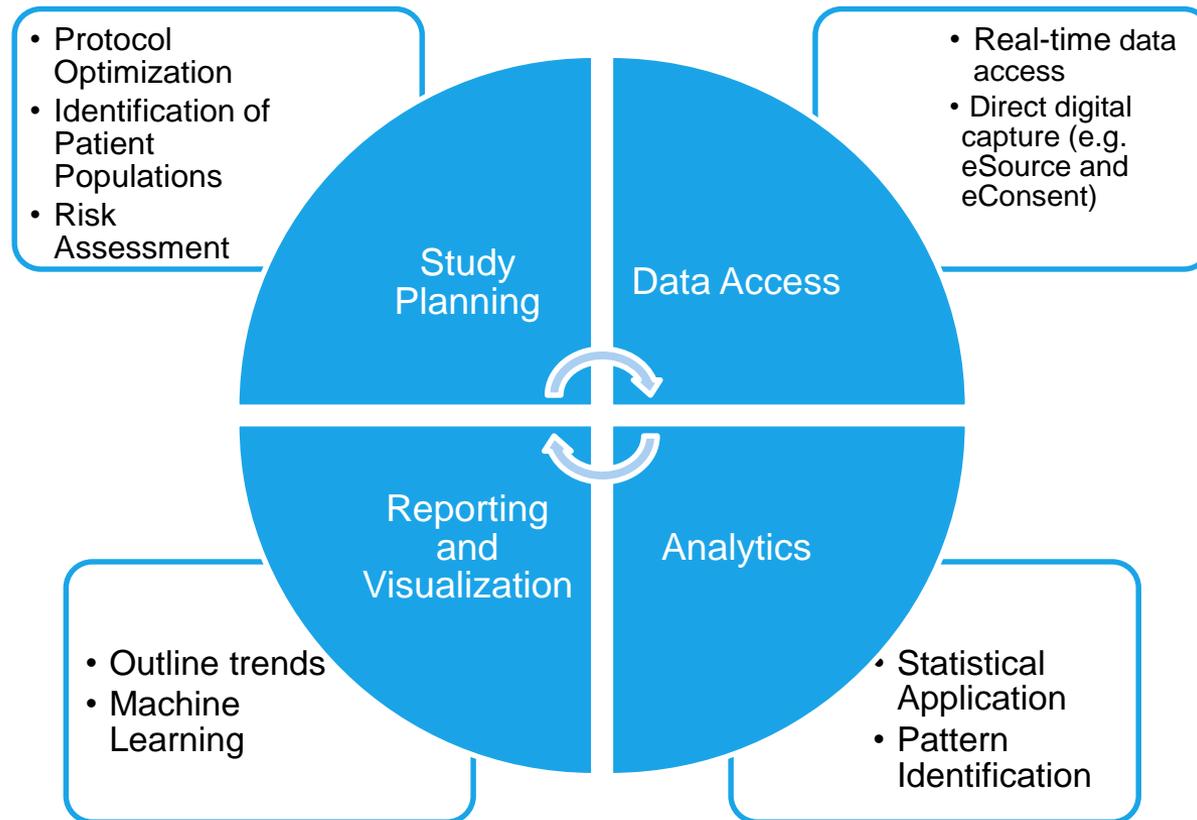


Continued...

- Previously with “Traditional Monitoring”, it would take months to reveal safety issues.
- Project managers previously relied on the monitoring reports for their information, the reports were submitted after the monthly on-site visit.
- The implementation of Centralized Monitoring and technology has allowed for faster informed decision making and improved subject safety.



Future of Centralized Monitoring Technology



Polling question #3

- Do you understand the impact of Centralized Monitoring at your site?
 - a. Yes
 - b. No
 - c. Better than I did before this webinar

Expected Benefits of Taking the Path

- Fewer Audit critical findings, than with traditional monitoring = *Fewer 483s*
- More timely review of data = *Faster decision making*
- Quicker identification of issues and remediation before the mistakes are repeated = *Fewer deviations and fewer repeat mistakes*
- More time for CRAs to work with sites on root cause and process improvement = *Enhances data Quality*
- Sites spend more time with their subjects and process improvement = *Greater Subject Centricity*

Questions?

- Please submit now using the Q&A function. We want to hear from you!
- Upcoming webinar: the last in this four-part series! Next Thursday, April 12 at noon ET –

Module 4: An Exploration of Risk Based Monitoring
from the Site Perspective

(If you registered through SCRS to attend this webinar, Module #3, you should have received a link to sign up with WebEx for module #4 as well!)

ICYMI: <http://myscrs.org/shop/a-clinical-trial-odyssey/>

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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