Risk-based Monitoring
Why Does it Matter to Programmers?



Shafi Consultancy Ltd.

Overview

- What is Risk-based Monitoring?
- Current thinking
- Why it matters for programmers?
- What should programmers do?
- Summary





Shafi Consultancy Ltd.

What is Risk-Based Monitoring? - Background

- Quality risk management => Eliminate risk
- 100% Source Data Verification (SDV)



- Very little key data is changed after 100% SDV



What is Risk-Based Monitoring? - Background

- On-site monitoring is almost 1/3 of the total cost



- On-site monitoring is more than just SDV

- Limited time/resource vs. Quality risk



What is Risk-Based Monitoring? - Regulatory direction



Shafi Consultancy Ltd.

What is Risk-Based Monitoring? - New Approach

- Moving from a manual and subjective process to an automated and logical process
- Programs can identify key data issues to check:
  - Identify risky sites – sites with problems
  - Target data to verify with SDV – not 100% SDV
  - Program a wide range of checks, including fraud
  - Perform checks more frequently on updated data

What is Risk-Based Monitoring? - New Approach

- Using programs, identify the risky sites and spend more resource on these, and less resource on sites which are proven to be less risky
- By targeting sites, this in effect is balancing risk with quality of the site
- The automated programs will monitor the quality of each site in relation to others over time

What is Risk-Based Monitoring? - Summary

- Automated checks
- Less manual effort
- Less resource
- Low COST
- High QUALITY



- 100% SDV
- Manual effort
- Resource intensive
- High COST
- Questionable effectiveness

Shafi Consultancy Ltd.

Current thinking by programmers

- It has nothing to do with us
- Data management takes care of this, we do the reporting after the database is clean
- We are too busy to get involved in everything

Why it matters for programmers

- This is a new avenue to increase programming requirements
- Programmers are under pressure to cut cost, but far more than the total reporting budget can be saved by taking a risk based approach
- This is one of the biggest new change coming to the industry, and these will need to be programmed, if we do not get involved other companies will be brought in to do this work

What should programmers do?

- Stop doing nothing
- Discuss with our Data Management, Statistician and Clinical colleagues about considering a Risk-based monitoring approach
- Take the lead and investigate the various centralized monitoring checks and reports that needs to be done in order to help the CRAs
- Increase the role profile and relevance of the programmers within the organisation

Summary

- Risk-based monitoring is here now, it not only improves the quality of the data, but does this by significantly reducing cost
- A great deal of programming is required to perform all the various checks, produce the many different reports and to calculate the risk of each site
- At a time of cuts and budget pressure, this is a new opportunity to increase the profile of the programmers within the organisation

Questions or Comments



Shafi Chowdhury

shafi@shaficonsultancy.com

www.shaficonsultancy.com

Shafi Consultancy Ltd.