

Risk-based Source Data Verification PhUSE Conference 2012, Budapest



 Shafi Consultancy Ltd.

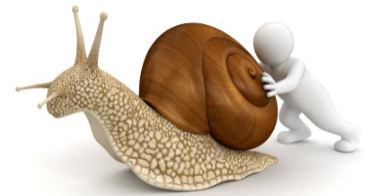
Overview

- Current process
- Centralised monitoring
- Risk-based SDV approach
- Why we should use risk-based SDV
- Summary



Current process

- Quality risk management => Eliminate risk
- 100% Source Data Verification (SDV)
- Less than 1% of data is changed after 100% SDV



Current process

- 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



Regulatory direction



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Centralised monitoring

- 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

Centralised monitoring

- 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

Risk-based SDV approach

- Define criteria for risk and assign risk to each site
- Assign risk based on:
 - Number of data issues
 - Length of delay in entering data after a visit
 - Fraud checks, inconsistent/missing data
 - Dropout rates
 - CRA feedback and previous history of co-operation



Risk-based SDV approach

- Based on the risk define:
 - What % of patients to verify 100% of the data
 - How often to visit a site
 - How long to spend at the site for monitoring
- UPDATE RISK based on new data
- Define which data to check, e.g. SAEs, outcome events, primary endpoint, demographic



Why we should use risk-based SDV

- Aim is to ensure QUALITY of trial and data
- Monitors have more time to focus on key issues to ensure GCP, compliance and overall quality
- More effective on identifying systematic and problem data than by eye – especially when rushed for time
- COST – less data to verify => less time

Summary

- 100% SDV is not a regulatory requirement
- Risk-based SDV approach can deliver better quality by a more targeted and focused effort to identify and resolve issues
- Automated programs can perform more checks and more often than possible with 100% SDV
- The larger the trial the more SAVINGS that can be made without compromising on QUALITY

Summary

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



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

Questions or Comments



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