Clinical trial monitoring: towards establishing best practice?

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Outline

• Recent developments
• Cross-hubs project on trial monitoring
• Survey of monitoring practice at CTUs
• Summary
Recent developments

MRC/DH/MHRA Joint Project ‘Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products’ 10th October 2011


Survey of practice (Morrison 2011)

Recommendations https://www.trialstransformation.org/projects/ctti-recommendations

Reflection paper on risk based quality management in clinical trials (draft) August 2011
Cross-hubs project on trial monitoring

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Cross hubs workshop aims

• Summarise current perspectives on monitoring in clinical trials
• Discuss examples of application of
  ▪ risk-based approach
  ▪ monitoring plans
  ▪ central monitoring
• Discuss the strengths and weaknesses of on-site monitoring
• Encourage networking of individuals with an interest in monitoring
• Stimulate development of future methodology research in this area
Workshop plans

- Workshop date: 10th May 2012 in Liverpool

- Contact list of one representative from 43/48 of the registered CTUs
  - Comments on draft agenda
  - On-line questionnaire circulated to all contacts
  - Information gathering (examples of risk assessment, monitoring plans and methods of central monitoring)
Current practice - CTU survey

- Norah Mawoko and Catrin Tudur Smith 2011
- On-line survey of 48 UKCRC registered Clinical Trials Units
- Only 23 (48%) complete responses – 22 involved with CTIMPs

CTU Role of individual taking survey

- CTU director/deputy
- Trial manager
- Trial monitor
- CTU manager
- Quality Assurance
- Other

Median 20 clinical trials per clinical trial unit (range 3 to 150)
Current practice - CTU survey

CTU Funding Source

<table>
<thead>
<tr>
<th>CTU Funding Source</th>
<th>% of CTUs</th>
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<tbody>
<tr>
<td>HTA</td>
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<tr>
<td>MRC</td>
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<tr>
<td>NIHR</td>
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<td>Diabetes UK</td>
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<td>Private Industry Funding</td>
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<tr>
<td>The Health Foundation</td>
<td>10</td>
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<td>Other</td>
<td>10</td>
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Current practice - CTU survey

- Risk assessment to determine level of monitoring: 53% all trials, 17% most trials, 26% some trials, 4% missing
- Monitoring plan: 35% all trials, 26% most trials, 30% some trials, 9% missing
- Most CTUs used some level of central monitoring, either with or without on-site monitoring
Current practice - CTU survey

Central monitoring methods used at CTUs

- Checks for missing data
- Plausibility checks
- Checks for unusual data patterns
- Calendar checks
- Other:
  1. Comparison with previously reported data
  2. Checking version control
  3. Delegation log tasks
  4. Central receipt and check of accountability logs
  5. Informed consent forms
  6. Checking training logs
  7. Compare recruitment rates between centres
  8. Compare withdrawal rates and reason between centres
  9. Compare the nature and percentage of SAEs between centres
  10. Compare the percentage of data queries between centres
Current practice - CTU survey

Perceived benefits of central monitoring

- Cost effective
- Reliable
- Easily accessible
- Not applicable
- Other

% of CTUs
Current practice - CTU survey

Perceived limitations of central monitoring

- Lack of Financial Resources
- Lack of Qualified Staff
- Lack of Time
- None
- Not applicable
- Other

Chart showing the percentage of CTUs with perceived limitations in each category.
Summary

• Increasing support for risk based approaches and central monitoring
• CTUs are using these approaches already
• Wealth of information and practical examples available from CTUs
• Need a forum to
  ▫ Share practice and current perspectives
  ▫ Discuss areas of methodological research
  ▫ Move towards establishing an evidence base for best practice