

# Clinical trial monitoring: towards establishing best practice?

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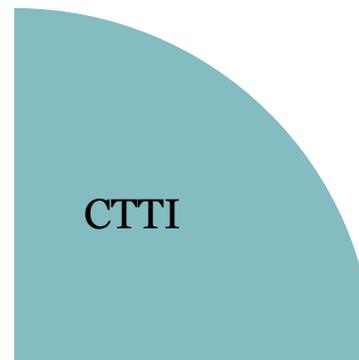
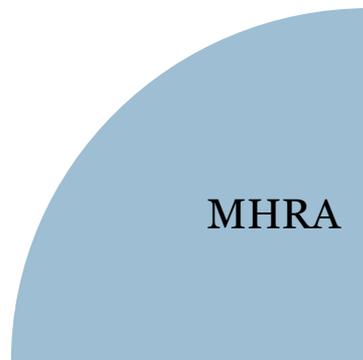
North West Hub for Trials Methodology  
Research

# 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' 10<sup>th</sup> October 2011

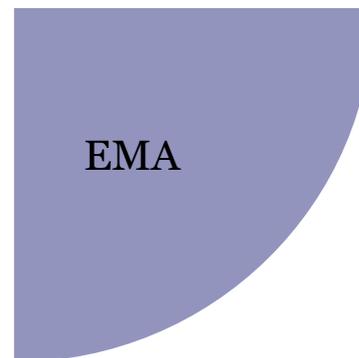


Survey of practice  
(*Morrison 2011*)

Recommendations

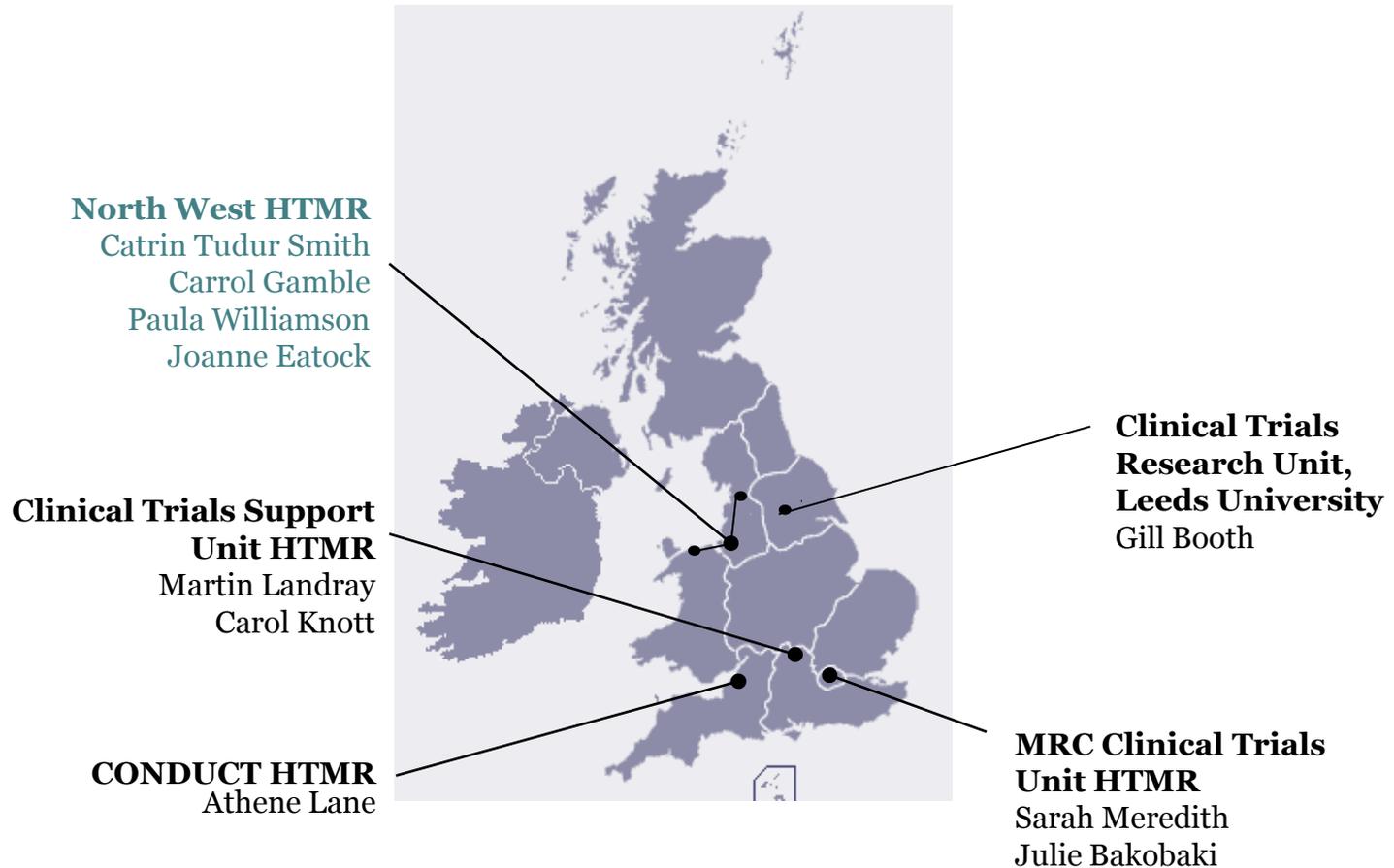
<https://www.trialstransformation.org/projects/ctti-recommendations>

Guidance for Industry, Oversight of Clinical Investigations – A Risk Based Approach to Monitoring. Draft Guidance August 2011 – comments closed end of November 2011



Reflection paper on risk based quality management in clinical trials (draft)  
August 2011

# Cross-hubs project on trial monitoring



# Cross hubs workshop aims

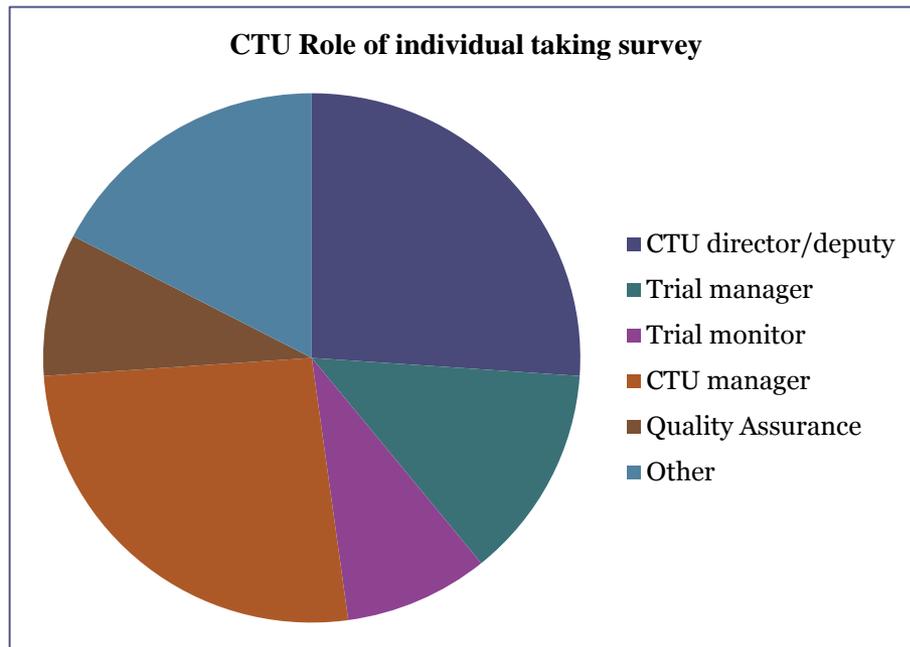
- Summarise current perspectives on monitoring in clinical trials
- Discuss examples of application of
  - risk-based approach
  - monitoring plans
  - central monitoring
- Discuss the strengths and weaknesses of on-site monitoring
- Encourage networking of individuals with an interest in monitoring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

# Workshop plans

- Workshop date: 10<sup>th</sup> 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)

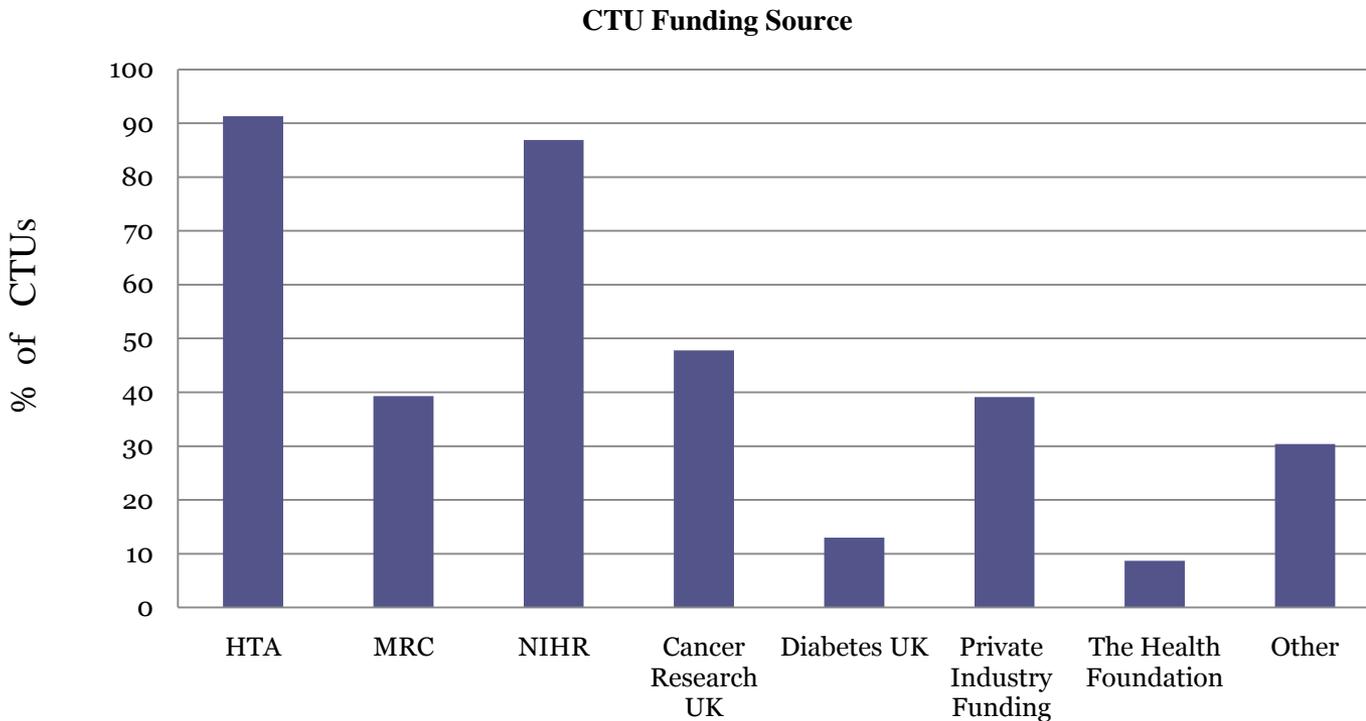
# Current practice - CTU survey

- 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



Median 20 clinical trials  
per clinical trial unit  
(range 3 to 150)

# Current practice - CTU survey

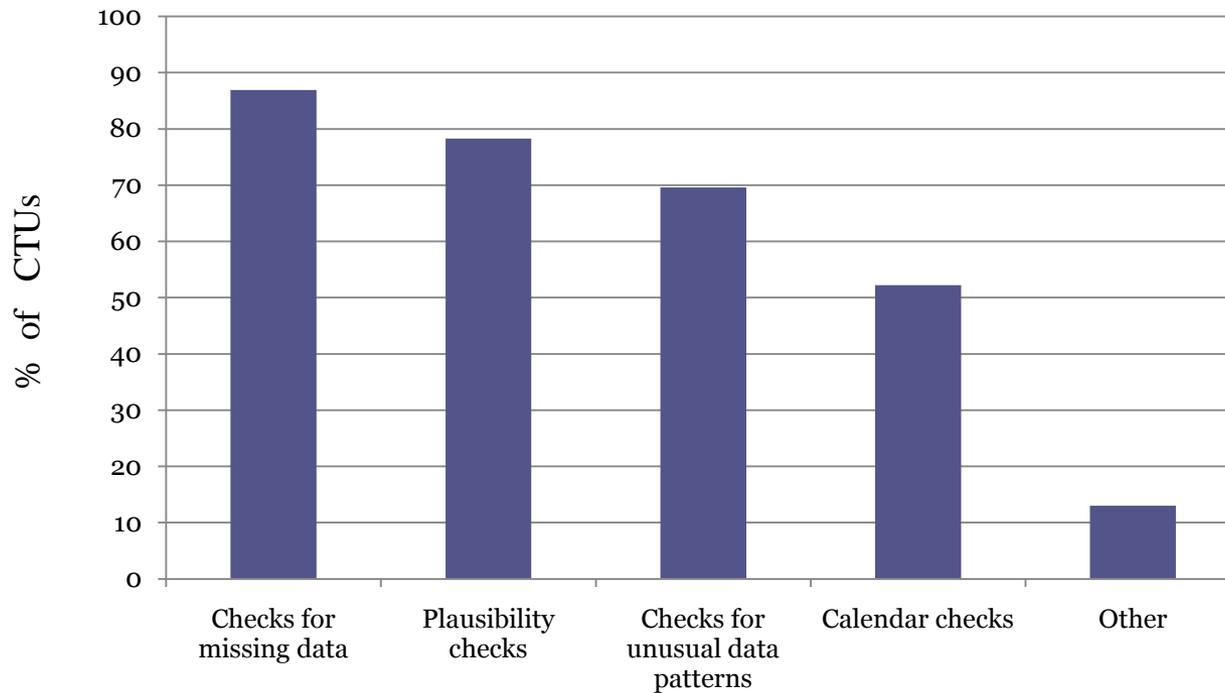


# Current practice - CTU survey

- 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

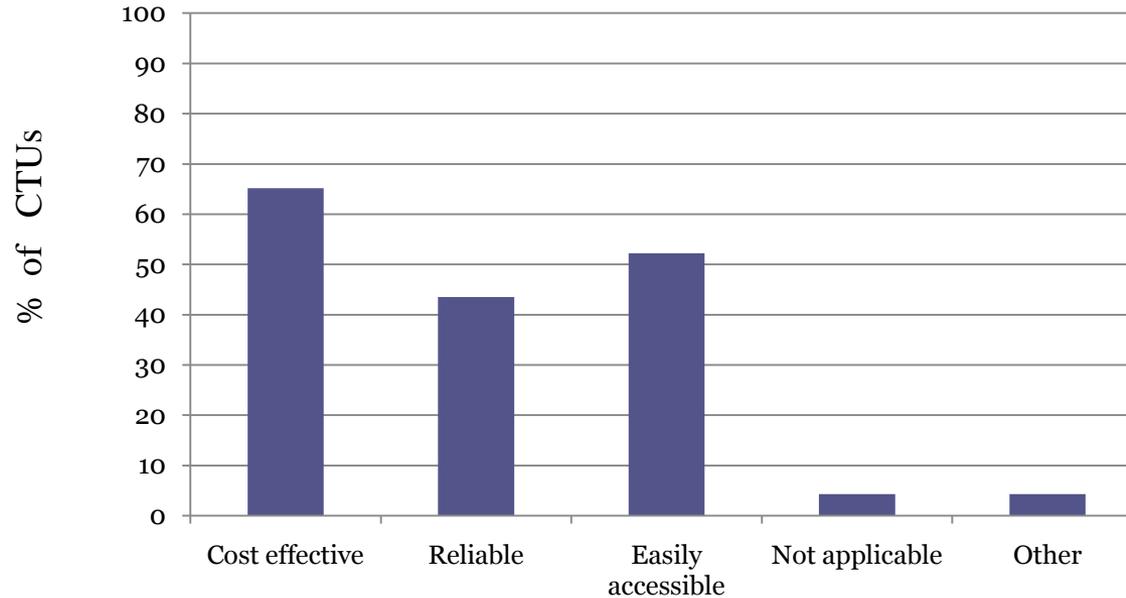


### Other:

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

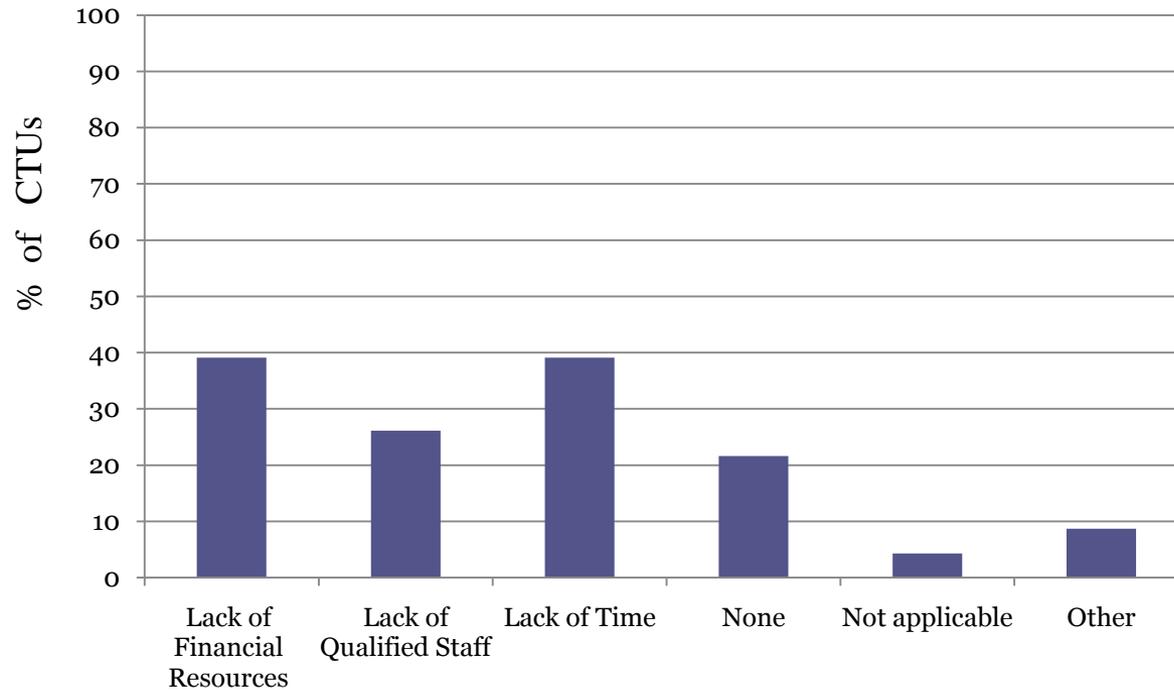
# Current practice - CTU survey

## Perceived benefits of central monitoring



# Current practice - CTU survey

## Perceived limitations of central monitoring



# 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