

CTTI RECOMMENDATIONS: EFFECTIVE AND EFFICIENT MONITORING AS A COMPONENT OF QUALITY ASSURANCE IN THE CONDUCT OF CLINICAL TRIALS

Primary Recommendations

Build quality into the scientific and operational design and conduct of clinical trials

Focus on what matters

- “Quality” is defined as the absence of errors that matter (i.e., errors that have a meaningful impact on patient safety or interpretation of results)
- Determine what matters for a specific trial

Develop a quality management plan

- Initiate plan in parallel with protocol development
- Focus on areas of highest risk for generating errors that matter
- Seek regulatory review of plan

Assess performance in important parameters

- Prospectively measure error rates of important parameters
- Tailor monitoring approach (e.g., site visits, central, statistical) to the trial design and key quality objectives

Improve training and procedures

- Based on measured parameters

Report findings of quality management approach

- Include issues found, actions taken, impact on analysis and interpretation of results
- Incorporate into regulatory submissions and publications
- Encourage inclusion in International Committee of Medical Journal Editors requirements

Ancillary Recommendations

Share knowledge and experience

- Collaborate among academia, industry, and regulators to share methodologies and data

Encourage appropriate regulatory guidance

- Emphasize key principles of quality trials (i.e., human subjects protection, reliable results, protocol adherence)
- Encourage risk-focused oversight of trials

Promote education and awareness

- Focus on those involved in design, implementation, analysis, interpretation, regulation, inspection, and publication of clinical trials
- Include users of results (e.g., health care providers, doctors, patients)

Seek international adoption and harmonization

- Facilitate global adoption of proposed changes

References

Landray MJ, Grandinetti C, Kramer JM, et al. Clinical Trials: Rethinking How We Ensure Quality. *Drug Information Journal* November 2012; 46:657-660.

Morrison BW, Cochran CJ, White JG, et al. Monitoring the quality of conduct of clinical trials: a survey of current practices. *Clinical Trials* June 2011; 8(3):342-9.

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- ▶ These recommendations are based on results from the [Monitoring](#) project.
 - ▶ CTTI's [Executive Committee](#) approved the recommendations.
 - ▶ Released in May 2011