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


These recommendations are based on results from the Monitoring project.
CTTI’s Executive Committee approved the recommendations.
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