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# Ensuring Quality In Medical Device Trials


**By Mary Lewis, Senior Clinical Research Specialist, IMARC**

Manufacturers have used a quality systems approach to ensure consistency within their processes for years, but the FDA is now encouraging clinical researchers to take a similar approach to medical device trials.

This is driven by several factors. First, the complexity of new medical device products, as well as the size and global nature of the trials, presents a greater potential for error.

Additionally, patients have more complex needs and conditions.

Ensuring the quality of medical device trials ultimately means protecting human subjects, ensuring regulatory compliance and ensuring data integrity.

Although sponsors and principal investigators are ultimately held responsible for this, a quality systems approach should involve input from all relevant parties, including the FDA, sponsors, IRB/ECs, monitors, sites and investigators and clinical vendors.

Here are five steps all research sponsors and their teams should take to ensure the quality of medical device clinical trials.

**1. Review Protocol and Data Requirements**

Prior to the start of the study, the sponsor should review protocol requirements to be sure the study will answer the right questions, has appropriate eligibility requirements and includes appropriate procedures.

They should seek feedback from medical device experts. This may take the form of steering committees composed of clinicians, global or national principal investigators, clinical scientists or FDA reviewers, clinical monitors and biostatisticians. Consider asking the FDA to review and provide feedback on the data plan to be sure it meets guidance.

During protocol development, sponsors should also take steps to minimize protocol deviations. One example is designing data collection forms to gather numbers electronically rather than text fields to avoid misinterpretation or misclassification of data.

Taking these extra steps in protocol development can help sponsors avoid costly misunderstandings and protocol deviations later.

**2. Select Qualified Investigators**

A clinical investigator with expertise in medical device research can be a sponsor's best defense against compliance issues that can undermine the trial. Here are a few important questions to ask principal investigators:

- Have you conducted human studies before?
- Are you certified by a professional clinical research association, such as SOCRA or ACRP?
- What type of training do you have in clinical research regulations and guidances?
- What staff and resources do you have in place to conduct a clinical trial?
- What experience do you have with medical devices similar to this one?

Choosing the right investigator is just the first step. Sponsors also need to ensure investigators receive proper training before the trial begins. In addition to standard clinical research training that covers informed consent, human subject protection and regulatory requirements, investigators should be trained in study-specific protocols. If a particular procedure isn't standard, the sponsor should provide rationale for it.


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**3. Ensure Adequate Clinical Research Monitoring**

Quality clinical research monitoring is another crucial defense against data discrepancies and regulatory compliance violations. Frequent and early monitoring catches noncompliance sooner and provides an opportunity to course correct before study integrity is in jeopardy.

Select qualified clinical research monitors and promote the "everyone's a monitor" mentality. In some circumstances, risk-based remote monitoring may be more efficient and effective. Risk-based remote monitoring can be combined with traditional monitoring to catch large numbers of queries and late database problems.

Clinical monitors should routinely evaluate the following areas:

- Human subject protections
- Communication with the IRB/EC
- Protocol compliance
- Rationale for and documentation of protocol deviations
- Source data verification to ensure it is current, complete and accurate

While monitors are a critical second set of eyes, all clinical research professionals should understand how to properly document research as they go. Remembering the acronym ALCOA-C can help ensure they are following guidelines for proper documentation. According to 21 CFR 58.130 (e), all clinical research documentation should be attributable, legible, contemporaneous, original, accurate and complete.

**4. Ensure Investigator Compliance**

Concerns about the study can result in FDA refusal to accept site data in support of a marketing application. Work with the site to resolve compliance issues as they arise. While the FDA does not expect perfection when it conducts inspections, it does expect to see researchers implement corrective action to avoid repetitive occurrences.

**5. Conduct Internal Audits**

Quality assurance audits can help sponsors catch issues before an FDA inspector does.

Sponsors should consider conducting these audits periodically. Comprehensive clinical research auditing should cover every aspect of the site, including protocol, IRB requirements, agreements, sponsor requirements and standard operating procedures.

The results of these audits should be reviewed with the team to identify gaps in the process and provide opportunities for additional training and coaching.

Clinical researchers should expect a quality systems approach to become a standard part of their process, particularly in medical device clinical trials. However, a quality systems approach isn't merely another box to check. Sponsors, investigators, monitors and all involved with a trial should view this approach as a way to add a layer of protection for human subjects. They should see it as an opportunity to identify data and compliance issues earlier and continually improve upon their processes.

For more detailed guidelines on implementing a quality systems approach, download our whitepaper, Conducting Clinical Research in Medical Device Systems Utilizing a Quality Systems Approach.

## About the Author

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