BEST PRACTICES

A Collection of Best Practices for:

Pharmaceuticals

Includes Detailed Best Practices for:

- Research & Development
- Pharmaceutical Manufacturing
- Pharmaceutical Distribution
- Product Education & Compliance
- Patient Assistant Programs (PAPs)

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Pharmaceuticals Best Practices

Clinical Trials

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The testing phase of a new drug is a lengthy and expensive part of research and development. The Food and Drug Administration (FDA) demands that candidate pharmaceuticals pass through a three-phase process of human trials to demonstrate safety and baseline efficacy. The first two phases involve only small sample groups of test patients. The third phase involves a sample size of thousands of patients and carries huge costs. Generally, Phase III trials need to demonstrate that a drug meets the necessary efficacy requirements with a 95 percent statistical certainty.

Best Practice 1-A

Implement Proactive Measures to Ensure Clinical Trials Have High Levels of Enrollment

Implement proactive measures to foster high levels of clinical trial enrollment. For instance, screen patients across several clinical trial protocols, instead of just one, as it could accelerate subject/trial matching and the subject's willingness to participate by providing them with various study options that clearly identify risk/benefit and burden. Compare actual and projected enrollment data regularly to keep on top of any issues in the enrollment process or changes in trends that need to be addressed.

Typical Practice (the Status Quo): Contact known physicians when a trial is soon to be underway and have them recommend contact with subjects who might be willing to participate in clinical trials. Supplement physician lists with online lists potential candidates can use to enroll (ensure that candidates contact the pharmaceutical company to obtain study-level materials). Once trial subjects are obtained, screen them for a single clinical trial protocol and inform them of any decisions made to include them on the study.

Benefits of this Best Practice: Since most clinical trials are plagued with slow enrollment, implementing proactive measures (use of patient advocacy groups, highly targeted search engine optimization, pay-per click advertising, etc.) ensures that clinical trials have enough potential candidates to start on time. These measures, such as screening patients across several clinical trial protocols, also allows candidates to be included in more than just one clinical trial and fosters candidate engagement by connecting and educating them. Furthermore, continuous monitoring of clinical trial enrollment ensures that any changes in trends or enrollment issues can be analyzed and resolved quickly and efficiently.

Related KPIs: Cycle Time: Clinical Trial Enrollment Quota, Percentage of Clinical Trial Work Outsourced, Clinical Trial Cost per Patient

Best Practice 1-B

Perform Routine Reviews of Data During Each Trial Phase to Improve Data Quality and Accuracy

Perform routine reviews of data, whether remotely or during a monitoring visit, during each trial phase. Identifying data quality issues early on allows discrepancies to be addressed and resolved before they can grow into significant problems. Furthermore, by retraining site personnel and establishing preventative measures, similar issues can be averted, thus increasing data quality and accuracy.

Typical Practice (the Status Quo): Perform data quality reviews after each clinical trial phase is complete. Major discrepancies should be explained, documented and resolved, if possible. If a data-related issue is unable to be resolved, attempt to restart the clinical trial phase to acquire new data.

Benefits of this Best Practice: Routine data quality reviews performed while each clinical trial phase is running not only prevents small discrepancies from growing into unmanageable problems, but also ensures that the quality and accuracy of all resulting data is