APPROUCH TO RISK ESTIMATION OF PROJECT MANAGMENT IN CLINICAL TRIALS

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Project management in clinical trials is the application of knowledge, skills, tools, and techniques to project activities in order to meet or exceed stakeholder needs and expectations from a drug development process.

An effective way to avoid expensive delays in approval timelines due to quality issues is early detection and mitigation of this risk by close monitoring and optimizing of the three parameters: quality, time, and cost

Processing the data maintained in various operational and clinical databases, against a predefined set of standards and metrics in a systemic way, is the first step in development of a rich repository of both historical and current compliance information. The step involves developing metrics to further derive base quality performance indicators (BQPI) for each parameter. With the BQPIs in place, by developing a process to continually monitor and update each parameter, a sponsor can achieve two objectives. First, it can optimize timelines or cost, while continually monitoring for changes in the quality. Second, any significant deviation from the mean (caused by an underlying change or signal) in any of the three parameters can be differentiated from background noise. The information obtained in this way can then be used to drive development cost and timeline reduction at an organizational level, while at the same time the quality of the output is intensively and efficiently monitored.

Development of accurate metrics and BQPI s for all three pillars of an operation (quality, timeline, and cost) combined with the implementation of an information management strategy such as text mining are essential elements for implementing this methodology. Combination of processes and systems that allow for early signal detection and the subsequent intervention is the true power of a data-driven quality management system**.** Compared to the benefit for the entire clinical organization, the investment in the technology is minimal. Selected parameters that indicate nonconformance can be obtained through all stages of product development. In combination with easy access to extensively trended information (operational BQPIs) and overview of financial BQPIs, this system provides a safeguard for sponsors to maintain an overview of the quality of their clinical operations in a cost-effective manner.