Bringing Process Efficiency TO CLINICAL TRIAL RANDOMIZATION

Modern business has fully embraced the benefits of process efficiency. From the widespread adoption of process improvement as driven by Michael Hammer, author of "Reengineering the Corporation," its evolution to the Six Sigma movement, to the more recent "lean sigma" approach, process efficiency has become a business goal for most organizations. The benefits of efficient processes are found in lower costs, faster execution times, and higher quality.

A well-known example occurs in the automobile industry where parts needed by assembly line workers are delivered to them at the moment the car being assembled moves by their location. This practice minimizes variation in worker movement, increasing efficiency in installing the parts. Furthermore, the available car variations (called "options") are limited for each model because the practice of improving processes teaches that "variation kills." What variation kills is the process' efficiency and concomitantly its low cost, fast execution and low error rate. The more variation allowed in the process itself or in the inputs to the process, the more susceptible it is to delays, higher costs, and lower quality.

Today's Randomization: The Antithesis of Efficiency

Consider today's process of clinical trial randomization. Here a widely varying set of clinical procedures and methods for choosing and processing subjects are incorporated in the trial design, part of the protocol. A key part of the design — the randomization — figures prominently in testing the hypothesis specified in the protocol. Randomizing the trial requires choices of arms, factors, and number of sites and patients for the trial. In most trials today, the variable inputs, such as arms and number of sites, are incorporated in a custom software program that guides the selection of subjects for the trial and prescribes the logistics for the provision of supplies to the investigative sites.

So here we have the worst of all worlds for process efficiency: highly variable inputs programmed into a highly variable software system. In most current practice, each software system must be individually developed and assembled to meet the needs of the protocol and trial sponsor. This is the antithesis of good process practice and is characterized today by high cost, high delay, and a high likelihood of error.

From a process perspective, how could this arrangement be improved? First of all let's recognize that the protocol's variation will be quite difficult to control. The protocol is designed to meet stringent scientific needs in proving a hypothesis and, as such, will be resistant to efforts to simplify and standardize. However, for the software that generates the randomization and logistics for the trial, a much better approach can be used.

Taking a New Approach

The better approach is to use software that is pre-written, pre-tested, and pre-validated for the purpose and thus exhibits no variability when used. This type of software is adapted, or configured, to the needs of the process through the input of variables that define the specifics of the process. As long as the variables occur within pre-tested ranges the software will perform correctly. In the case of clinical trial design, configurable software has recently become available. With this software, the creation of the randomization and logistics plans has been made quite simple. The trial designer knows the desired arms, factors, strata, number of sites and subjects and so on from the protocol. These data are input to the configurable software via an easy-to-use visual interface. Once the variables are provided, the software is ready to run in randomizing subjects and managing supply logistics. A process currently taking many weeks with conventional methods now takes only a few hours or less. Trial delays frequently experienced in creating the custom software are gone because the new software itself does not change from trial to trial — only its configuration changes. Errors and consequent reprogramming are virtually eliminated because the software has been validated in advance.

As an additional benefit, the configured software design can invoke a companion software program that simulates the trial operation and can immediately test the balance achieved between its arms, factors and other variables. The testing confirms the balance among arms or factors, for example, which has been achieved in the design. If an adjustment is needed to achieve a better balance, the design can be immediately redefined with different input variables and the simulation run again.

Such clinical trial innovation promises to bring new levels of process efficiency to trial design and trial execution enabling faster trials, lower costs and fewer errors. PV

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