

Responsibilities and Required Skills of Clinical Statisticians in Clinical Trials Processes

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Abstract

From conducting clinical trials till regulatory submissions, a clinical statistician is responsible for trial design, sample size calculation, protocol writing, case report form designing, randomization, analysis plan and mock outputs creating, data cleaning, outputs finalization, and clinical study report reviewing. Throughout these processes, statistician collaborates with different function groups daily, such as physician, compound lead, data manager, project manager, programmer, and medical writer. In addition, there are also interactions with different vendors and regulatory agencies. Therefore, a clinical statistician required to not only have solid knowledge on statistical methodologies, data presentation, and clinical background, but also great communication skills and trial experience.