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Study Start Up for a Global Phase III study: A case study on a global multicenter Phase III CNS studies

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Starting a global multicenter phase III study in Schizophrenia is challenging for many reasons. Understanding the patient population, regulatory landscape, access to clinics/physicians, study drug import/export permit and legal requirements are key during the planning phase of a global study. Selecting clinical trial sites are often a cumbersome process and traditional ways of conducting site feasibility are neither user friendly nor time sensitive. In such situations, it is very important to be creative on finding ways to collect the same information in a time and cost effective manner while ensuring the quality is not compromised. We at Alkermes came up with creative methods of conducting site feasibility and selection which in return reduced our site selection timeline during conferences and investigator meetings. Negotiating clinical trial agreements and budgets could easily take months to finalize. Using tools such as smart budgets, grant plan parameters for fair market value have allowed Alkermes to expedite the budget negotiation process. Similarly, liaising directly with clinical trial sites that are huge academic institutions have reduced contract negotiation timelines. Revising requirement for site essential documents and using online cloud based portals for document collection, tracking and tracking has improved site selection and start up. Use of technology such as remote study drug adherence or electronic-consents will reduce time lost and maintain. This presentation will showcase individual case studies of Study Start Up challenges and ways to overcome them maintain quality, time and costs.

Biography

Sid Chowdhury has completed his Bachelors in Pharmacy at the age of 22 years from Mumbai University, Mumbai and Masters of Science (MS) from Northeastern University, College of Professional Studies, Boston, MA. He is the Study Start-Up lead for Alkermes, a premier pharmaceutical company based out of the Boston metro area. He has been managing Study Start-Up for global Phase III CNS studies for more than 3 years and has been serving as a Clinical Trial Manager, Global Clinical Services.

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