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Fair market value and grant plan: Tool for negotiating clinical trial site budgets

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What is Fair Market Value? Fair Market Value (FMV) means paying a legitimate and reasonable market price to conduct studies per “industry standards” to limit bias into clinical trials. A grant plan is a benchmarking tool to inform a FMV decision. Grant plan is a representation of average fair market value costs. As a pharmaceutical company, we must ensure that payments for our Clinical studies should align with FMV for necessary services. Now there are many factors that affect the grant plan globally. A comparison on cost per patient between US and Ex-US sites show that it is more expensive to do clinical trials in the US. Likewise, a comparison between Western European and Eastern European countries reveal that it Western Europe is more expensive to do business. Geographic location, study indication, and design all attribute to a variation in the costs of doing business. How does a pharmaceutical sponsor company stay compliant with FMV? This presentation will explain Grant Plan parameters and smart budgets to negotiate clinical site budgets. A comparative case study(s) of Alkermes trials and the factors that impacts site budgets or cost of doing business will be discussed along with measures Alkermes took to stay compliant with FMV.

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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