Statistical Plan

Safety and Efficacy Study of the Effect of Etanercept in Hemodialysis Patients

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Statistical Plan:

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Protocol Name:	CCRC: The Independent Effects of Level of Kidney Function and Body Composition on Establishing HDL Cholesterol levels
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Subject: Outcomes/Statistical Plan

Mortality of patients with end stage renal disease (ESRD) remains a significant problem, and is associated with poor nutritional status, as indicated by low serum albumin concentration. Markers of malnutrition correlate with C-reactive protein levels, suggesting that inflammation plays an important role in determining nutritional status. This study was designed to examine whether etanercept can safely suppress the inflammatory response in patients with ESRD who have poor nutritional status, and whether this suppression will improve nutritional status and clinical outcome.

The study has been slow to accrue patients due to the large number of inclusion and exclusion criteria. At the request of our sponsor, Amgen, the inclusion, and exclusion criteria are extremely stringent to optimize safety. We consider the safety of the patients to be of greater importance than the speed with which the study is completed. In this diverse population of hemodialysis patients, approximately half the patients have advanced diabetes mellitus. Overall, the morbidity of the population is extremely high, and many of the patients have been exposed to a variety of pathogens, including hepatitis (B or C) and tuberculosis, or have tunneled dialysis catheters. The latter three exclusions have accounted for the greatest number of ineligible patients.

Albumin, C-Reactive Protein, and Prealbumin were to be analyzed by linear regression. This analysis was not done due to our inabilities to recruit eligible patients within our recruitment criteria.