

PREDICT-1 (CNA106030): THE FIRST POWERED, PROSPECTIVE TRIAL OF PHARMACOGENETIC SCREENING TO REDUCE DRUG ADVERSE EVENTS

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Pharmacogenetics (PGx) is becoming an increasingly important research tool as physicians, patients, regulatory authorities and payers look for innovative ways to improve the risk:benefit ratio of medicines. One area where significant progress has been made is in the identification of PGx markers associated with variable response to antiretroviral medicines. For example, the major histocompatibility complex HLA- B*5701 allele has been associated with hypersensitivity to abacavir by several independent researchers. However, this association between HLA-B*5701 and abacavir hypersensitivity has been identified largely through retrospective examination and in order to assure the medical and scientific communities of the clinical utility of this marker in patient care, a prospective, randomized study was required. This talk will outline the design of the study to evaluate the utility of prospective screening for HLA-B*5701 to reduce the incidence of abacavir hypersensitivity. The talk will also discuss statistical design issues considered during the development of the protocol and will present statistical analysis results. As the first fully powered, randomized, blinded, prospective study to determine the clinical utility of PGx screening to reduce drug-associated adverse events, the talk will further discuss methodological lessons learnt for future PGx researchers.