Phase 3 study examining adjunctive armodafinil for the treatment of a major depressive episode associated with bipolar I disorder (NCT01072929). METHODS: To assess the safety and efficacy of adjunctive armodafinil 150 mg/day in a heterogeneous sample of patients, this 8-week, double-blind, placebo-controlled, multicenter study evaluated adult patients with bipolar 1 disorder who were currently experiencing a major depressive episode while taking 1-2 maintenance therapies (and/or second-generation antipsychotics). RESULTS: The study was conducted at 70 centers in 10 countries from January 2010 to March 2012. Of 786 patients screened, 433 were randomized. Baseline disease severity as assessed by mean (SD) IDS-C total scores was characteristic of moderate depression (43.6 [6.93]) and 43.2 [7.76] for the placebo and 150 mg groups, respectively. The most common concomitant treatments were valproate, lithium, and lamotrigine. Patients in the placebo and armodafinil 150 mg group experienced their first depressive episode 19.8 (SD 10.24) and 19.4 (SD 11.73) years prior to screening, respectively. The number of distinct regions of adjudicated treatments will also be reported. CONCLUSIONS: Because the design allowed the identification of the variables as a result of changes in the exogenous variables.

PMR215 INVESTIGATOR-INITIATED APPROACH TO ADDRESS AN OPTIMIZATION PROBLEM IN DESIGNING COST-EFFICIENT STUDIES

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OBJECTIVES: To improve research productivity in an economic environment with limited resources, researchers may need to consider investigator-initiated approaches to design cost-efficient studies. A cost function was developed to guide decisions about trade-offs to be made in clinical trial design with the objective of minimizing cost while achieving a given level of power to detect differences in patient-reported outcomes. METHODS: The design and conduct of a clinical study was treated as a constrained optimization problem. A cost function was developed, and a Lagrangian function was constructed. First-order partial derivatives were taken with respect to each variable (e.g., number of recruitment sites, number of follow-up visits, and study duration). Comparative statics analysis was used to examine the changes in the cost variable as a result of changes in the exogenous variables. RESULTS: A necessary condition to minimize cost while achieving a given power is the equivalence of the ratios of the marginal cost associated with increasing each choice variable and the marginal change in cost associated with each choice variable, in other words the same cost per unit of output created by each input at the margin. For second-order condition, we made the reasonable assumption that increasing the number of participants recruited leads to a decrease in the marginal rate of change in the Type II error which holds. Comparative statics analysis showed that the increase or decrease in the rate of recruitment, expected percent loss to follow-up, and the cost of interventions lead to different trade-offs in outcomes in patients who had failed at least once line of therapy. CONCLUSIONS: In light of funding challenges, researchers could consider the trade-offs required to achieve a cost-efficient study for a given level of power using methods from economics and optimization.

PMR216 MULTI-NATIONAL RETROSPECTIVE CHART REVIEW STUDIES: LESSONS LEARNED FROM APPLICATION OF METHODOLOGY TO INTERNATIONAL EVALUATIONS OF BURDEN OF ILLNESS AND DRUG UTILIZATION AND SAFETY

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OBJECTIVES: In the absence of suitable health care databases, chart review studies can result in tailored datasets suitable for evaluations of burden of illness, unmet need and drug utilization and safety. This methodology, however, is associated with significant design and operational challenges. METHODS: Design and operational parameters of ten recent clinical trials and/or drug utilization and safety studies that evaluated the role of a variable is to be minimized or accounted for in the study design relating back to the health economics objective of the T&M study. For instance, clear definition of processes to be observed and thorough training help limit inter-rater variability. On the other hand, limiting data collection to a homogenous sample of centers and patients (i.e., specific patient and process characteristics), while minimizing the variability in study design and population, can compromise generalizability of the results. In situations where a medical intervention can be used to treat a broad range of patient populations with distinct clinical characteristics, limiting data collection to a certain subgroup means generating results applicable to these patients only. CONCLUSIONS: Variability can be controlled through thoughtful study design. However, significant confounders should be identified and accounted for to produce valid process time estimations. Proper handling of variability in time measurement will improve precision of the duration estimates in support of health economic analyses.

PMR217 THE VALUE OF A GOOD DECISION: ASSESSING THE ECONOMIC BENEFITS OF DECISION AIDS

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OBJECTIVES: Decision aids are increasingly used to support doctors and patients in shared decision making. However, the true benefits of decision aids are difficult to measure. Studies that have evaluated the economic impact of decision aids have received limited attention. Significant non-health benefits such as improved patient knowledge, experience and satisfaction may accrue through the use of decision aids. These cannot be assessed within the dominant health economics framework. The objective of this paper is to provide a new opportunity cost-based method suitable for assessing the benefits of decision aids relative to other interventions in a resource-constrained health care system. A literature review has identified how decision aids have been evaluated found that economic evaluations are limited. Non-health benefits