

## 4<sup>th</sup> International Conference and Exhibition on **Pharmacovigilance & Clinical Trials** August 10-12, 2015 London, UK

### **Recruitment and screening for a multi-site sleep clinical trial: Rolling wave planning leading to study success**

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Screening steps of unknown failure rate in a Phase I trial can lead to misestimation of study activity parameters such as recruitment, time, and cost. We set out to develop a model of study planning that would permit the iterative estimation of these activities. First estimates were based on a 53% success rate at Screening Visit 1 (medical history, study criteria), and 66% for Visits 2-3 (sleep problem screening). Multi-step screening of participants with iterative, rolling wave planning was deployed to accurately adjust the flow of volunteers at Screening Visit 1 to adapt to the failure rate at each screening step. The goal was to maintain the right flow of eligible volunteers without surpassing the sleep center bed capacities as the study protocol allowed a strict time window between each visit. Reactivity of the recruitment team was paramount to promptly adjust study activities in response to screening rates communicated. In total, 640 subjects went through Screening Visit 1; of those, 190 qualified and completed Visit 2. Visit 3 was performed on 160 prequalified subjects as per Visits 1 and 2. Of those, 52 subjects were eligible and were randomized. Corrected screening statistics were: 30% success rate at Screening Visit 1, 84% at Visit 2, and 33% at Visit 3. This equates to a challenging overall 8% success rate for this healthy subject sleep trial. Challenges of a multi-step screening for a study with extreme filtering inclusion criteria and strict timelines were successfully met through rigorous communication, and rolling wave planning.

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### **Health professional students' knowledge on pharmacovigilance (PV)**

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Spontaneous reporting of adverse drug reactions (ADRs) has a critical role on public health. Pharmacovigilance (PV) system tries to minimize the potential health risks, outcomes of medicine consumption for public. The aim the study is to raise the knowledge and awareness of the health care professional students on PV. An education presentation is prepared by the researchers and approvals and appointments are done via faculty professors. Between February 2014 and April 2014 trainings have been conducted. The 3rd and 4th class students of the pharmacy, nursing, nutrition and dietetics, physiotherapy and rehabilitation departments have participated. 8 different conference each took 20 minutes and 234 students have participated. A survey was applied, awareness and opinions of the PV before and after the education was measured. The knowledge of PV, reasons for not reporting, appreciated to the education were evaluated. According to results, 50% of students declared that they have never heard PV system. After the training section, 91% of the students reported that PV system/spontaneous reporting is helpful for detection and protection from ADRs. Academic researchers should not only conduct scientific study but also inform and involve in social interactions so as to promote public health. The results suggest that PV training and education sessions for health care professional students are needed to be increased for the knowledge of PV and to foster positive attitudes toward adverse effects of drugs.

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