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International Conference on

Toxicology and Pharmacology

November 01-02, 2017 | Toronto, Canada

Evaluating the abuse potential of CNS active drugs: Regulatory and methodological considerations

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Prescription drug abuse continues to be a great concern and regulatory agencies such as the FDA and Health Canada require abuse potential evaluation to inform appropriate drug scheduling for novel CNS-active drugs at the time of drug approval. One of the required studies includes the human abuse potential study (HAP). HAP studies are a type of clinical study evaluating subjective and objective drug effects related to abuse potential and drug impairing effects. The preferred design is a randomized, double-blind, placebo- and positive-controlled crossover study. The studies are generally conducted in drug-experienced, non-dependent recreational drug users who have a past and recent history of using a drug in the pharmaceutical class of the test drug. Generally, these studies are considerably distinct compared to healthy volunteer and patient studies, and host their own complexities and challenges. The drug using population represents a unique subgroup requiring adaptions to clinical trial methodology. Challenges with these populations include, but are not limited to, compliance with restrictions around concomitant medication and drug use, risk-taking behavior, and prior addictive disorders. The population needs to be carefully selected and screened to ensure that safety is not compromised, eligibility requirements are met, appropriate discrimination between the active control versus placebo is established, and that subjects are able to comply with the study requirements. Furthermore, a population using drugs by a specific route (e.g. intranasal, intravenous) may be needed if the clinical trial intends to study unintended routes of administration, as is often the case in studies evaluating abuse-deterrent formulations. Understanding the profile and nature of the population and the study requirements ensures appropriate rigidity in the methods and conduct of such studies. This session will provide an overview of the key regulatory and clinical methodological considerations in conducting HAP studies.

Speaker Biography

Beatrice Setnik has been working in the area of CNS research, clinical drug development and abuse potential assessment for over 16 years and is an expert in the area of abuse liability evaluation. She is currently the Vice President of Scientific and Medical Affairs at INC Early Phase and an Adjunct Professor with the Department of Pharmacology and Toxicology at the University of Toronto. She earned her Doctorate degree in Pharmacology and the Collaborative Program in Neuroscience from the University of Toronto in 2005.

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