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First-in-human studies – An examination of the evolving regulatory and clinical practices to ensure subject safety

First-in-human studies are a key milestone in drug development. In such studies, a drug already tested in a preclinical setting (*in vitro*, animals) is tested in humans for the first time. Study participants, who are often healthy volunteers, face an element of risk as the ability to predict the effects in humans is limited. In recent history, albeit in rare cases, study subjects have experienced serious harm in such trials. Regulatory guidelines have evolved following such events to ensure the safety and well-being of study subjects, and most recently in 2017 the European Medicines Agency (EMA) has revised its guidance on first-in-human trials. The revised guidance includes additional strategies to mitigate and mange risks for study subjects, including guidance for the calculation of the starting dose, rules for subsequent dose escalation and the criteria for establishing the maximum dose. The guidance also provides criteria to stop a study, review emerging data and handling of adverse events in relation to the study stopping rules. Over recent years, first-in-human studies have become increasingly complex and include multiple parts such as single-dose ascension, multiple-dose ascension, food interactions, different age groups or gender, proof of concept, or relative bioavailability of different formulations. As such data generated during the course of the trial should be carefully reviewed and used to inform the decision to initiate a subsequent study part or to inform the selection of the doses to be evaluated. This session will discuss the evolving requirements for conducting first-in-human studies and will focus on the key regulatory and clinical considerations in ensuring subject safety.

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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