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TITLE

CHALLENGES IN CONDUCTING BA/BE ASSESSMENTS DURING CLINICAL DEVELOPMENT OF ONCOLOGY DRUGS

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A large number of cytotoxic/genotoxic and targeted oncology drugs are currently in clinical drug development. In addition to the general challenges faced in drug development, one of the key challenge in developing a new oncology drug is assessing BA/BE during clinical development, as many of the newer oncology agents are for oral use. The BA/BE assessment challenge comes form genotoxicity of these agents, which means the assessment can be conducted only in cancer patients. As a result, BA/BE assessments are integrated in clinical trials in cancer patients. The presentation will cover ethical considerations for incorporating BA/BE assessments in clinical trials in cancer patients along with clinical operation issues that govern successful conduct of such evaluations. The presentation will also cover types of formulation development issues that are encountered during clinical development of oncologic agents along with combination of in vitro, pre-clinical and clinical BA/BE strategies that are applied to support the clinical development programs. Finally, importance of early understanding of the cause of pharmacokinetic variability and mitigating the issues of limited statistical power in assessing BA/BE for oncologic agents will be discussed.