Title: Project Optimus

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Abstract:

The FDA Oncology Center of Excellence (OCE) initiated Project Optimus to reform the dose optimization and dose selection paradigm in oncology drug development. This initiative is aimed at improving dosage selection for oncology products, which has historically relied on identification of the maximum tolerated dose (MTD) based on dose-limiting toxicity (DLT). Project Optimus emphasizes comprehensive evaluations of both the risks and benefits associated with treatment, rather than solely concentrating on DLTs and the MTD. To date, Project Optimus has participated in multiple public workshops and research efforts on dose optimization in oncology. In addition, members of Project Optimus have helped to publish the recent draft guidance, "Optimizing the Dosage of Human Prescription Drugs and Biological Products for the Treatment of Oncologic Diseases". This talk will discuss the status of some of these efforts and provide general regulatory perspectives on dose optimization in oncology.