Development of cancer immunotherapeutics creates some unique challenges for nonclinical safety assessment. These can range from lack of pharmacological activity in standard toxicology models to exaggerated pharmacology that can be dose limiting. This presentation will describe two case studies, one checkpoint inhibitor (atezolizumab) and one T cell dependent bispecific (CD20/CD3 TDB), to serve as an example of each scenario. Furthermore, nonclinical regulatory guidances and strategies to support clinical combinations containing cancer immunotherapeutics will be discussed.
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