

Module 9 Abstract: Evaluation of Potential Carcinogenicity *Basic Topics in Toxicology eLearning Seminar*

This presentation provides in a stepwise, orderly fashion the evaluation of potential carcinogenicity using rodents. Following a brief history of chemical carcinogenicity, the presentation outlines possible study objectives requirements for carcinogenicity studies set by regulatory agencies factors to consider in designing a strategy for evaluation using weight of evidence approach and predicting carcinogenicity. The presentation stresses specifics related to planning for carcinogenicity study, study design, internal and regulatory review of carcinogenicity study protocol and very importantly study oversight. The presentation concludes by addressing the interpretation of “positive” results for assessing human safety and the regulatory implication of a “positive” study.