

Evolution of the Exposure Response Guidance: Regulatory and Industry Perspective

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The FDA guidance on exposure-response (ER) encapsulates the thinking of the agency regarding the use of exposure-response analyses in regulatory decision-making. Since then the FDA has produced a number of initiatives that encourages the industry to apply innovative ER approaches to drug development with the purpose of speeding up development as well as containing cost. In addition the FDA Pharmacometrics group has recently published a number of articles summarizing the impact of the application of ER principles to the review process and drug development. This presentation briefly discusses the guidance and some of the issues that could be addressed in an updated version, such as ER as confirmatory evidence of effectiveness and the consequences of intermittent dosing. The recent publications by the FDA Pharmacometrics group will be discussed with respect to the influence these communications have on the pharmaceutical industry.