

1086-AE-2886 **Helen Moore*** (helen.moore@certara.com), 100 Mathilda Place, Suite 160, Sunnyvale, CA 94086. *Mathematics and Statistics in Drug Development*.

The Food and Drug Administration (FDA) requires extensive mathematical and statistical analysis of data before approving new drugs. Biotechnology and pharmaceutical companies use additional analysis for internal decision making. I will discuss some of the types of standard analyses of drug concentration data (pharmacokinetics) and drug effect data (pharmacodynamics). I will also mention some open questions and opportunities for new mathematical and statistical approaches to advance drug development. (Received September 26, 2012)