American Course on Drug Development and Regulatory Sciences

Substantial Evidence in 21st Century Regulatory Science

*Borrowing Strength from Accumulating Data*

April 21, 2016

Session 2/3 Panel

Chairs: Lisa LaVange, Karen Price, John Scott
Panelists

- Dr. Scott Berry
- Prof. Bradley Carlin
- Prof. Frank Harrell
- Prof. Steven Goodman
- Dr. Telba Irony
- Dr. David Ohlssen
- Dr. John Scott
Question 1

Our statutes (*) call for substantial evidence of effectiveness to support approval of new drugs. Traditionally, this has been interpreted as two adequate and well-controlled trials with statistically significant (p-value < 0.025 one-sided) results.

• Are Bayesian approaches to drug development compatible with this concept of substantial evidence?
• Can Bayesian approaches to drug development provide regulators with assurance that ineffective drugs are not approved?

*www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact
Question 2

Are Bayesian approaches in drug regulation a way out of the traps set by p-values, as described in the recent statement by the American Statistical Association?
Throughout Sessions 2 and 3 we have explored several examples demonstrating the value of the Bayesian approach and the importance of appropriately leveraging Bayesian methods for design and decision making.

- What specific actions should we take to increase the use of Bayesian methods for deriving substantial evidence of effectiveness?

- How can groups such as the DIA BSWG help?
Open to Audience/Additional Questions