# American Course on Drug Development and Regulatory Sciences

## Substantial Evidence in 21st Century Regulatory Science

***Borrowing Strength from Accumulating Data***

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UCSF

University of California, San Francisco
Schools of Pharmacy and Medicine
Department of Bioengineering
and Therapeutic Sciences

# 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?

# Question 3

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