

Pharmacokinetics and Pharmacodynamics as a Decision Support Tool for Setting Breakpoints:

A Workshop on Basic Concepts and Use

8 January 2011 3:30 p.m.-6:30pm in Cloister Room

Antibiotic PK-PD, Clinical Efficacy, and Breakpoints: An overview of how they are used in breakpoint decisions (**Mike Dudley- 30 min**)

- What is an “ideal” clinical dataset for setting breakpoints vs. real world data
- What should we expect these analyses to provide?
- What are the individual components related to BP assessment and how do they fit together?

Pharmacokinetic data for BP analysis (**George Drusano-30 min**)

- What pharmacokinetic data are important?
- Why estimates for interpatient variability in PK parameters are as important as the point estimate
- Normal volunteer vs. patient data
- Population pharmacokinetics

Pharmacodynamic Data from Mice and Men: Use and Calibration of Animal Models for BP Analysis (**William Craig-30 min**)

- How are efficacy endpoints from humans and animal models related?
- How does one determine which endpoints in animals are relevant for humans for a given drug class
- What efficacy target: static, 1 log, or 2 log drop? Survival?

Simulations and PK-PD Data for BP Assessment and Decisions (**Sujata Bhavnani- 30 min**)

- What is a Monte Carlo Simulation and how does it “work”?
- How is the target attainment rate determined?
- Sensitivity of changes in assumptions, targets on output and conclusions

Putting it all together: an example (**Paul Ambrose-20 min**)

- Discussion of a recent example of using PK-PD analyses for decision support for a BP recommendation.

Q&A/Discussion (**30 min**)