

Dose by Quintiles

Detectable Drug Levels

- Question 1: Appropriate assessment method and level of detection for drug levels
 - One company noted 0.5 ng/mg
 - FDA current feedback:
 - Use LC/MS or equally as sensitive method
 - LOQ – 1 ng/g
- Observed cytostatic drug ranges in lungs:
 - Paclitaxel was detected in the lungs at concentrations of 1.18, 0.203, 0.097 and 0.023 ng/mg at Day 1, 28, 60 and 90 respectively. The peak concentration achieved in the lung is within the cytostatic potency of paclitaxel.
 - These were after administering 1X safety dose (concentrations were higher with 3X safety margin dose)
- BSC – mortality for 100 ug

Ascertainment Bias per Dr. Varcoe

- Blinding
- Ascertainment bias – more intense surveillance of experimental group?
- Missing data