

Seattle Pharmacometrics Group

presents

*Pediatric PK Modeling using AMS Data and
PhysioPD™ Modeling of Ursodiol in a Neonate Clinical Trial*

by

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This talk will present a mechanistic PhysioPD model of bile acid metabolism and cholestasis in adult and pediatric populations. This model represents several methodological and practical advances.

- It was built entirely with literature data, including metabolomics and genomics data. This is one of the first known models to incorporate these types of data into a physiological model.
- The literature-based model accurately predicted clinical results, namely a separate population pharmacokinetic modeling analysis of the plasma ursodiol concentrations measured using Accelerator Mass Spectrometry (AMS) in a pediatric clinical trial.
- The Bile PhysioPD model was able to identify the specific transporters, genes and biologic mechanisms that are the most likely cause of the observed inter-individual variation in PK data.

The pediatric PK analysis using AMS is also an advance, and was previously presented at the 2010 ASCPT conference. See www.rosaandco.com/posters/rosaVitaleaASCPTposter2011.pdf.

Results from both models are being applied to develop methods for dose predictions and to facilitate drug approvals for pediatric populations. The PhysioPD modeling methodology, whether for adults or pediatrics, is broadly applicable across disease areas.