

Clinical Pharmacology Subcommittee (CPSC) Report

ACPS Presentation, October 21, 2003

Jürgen Venitz, MD, Ph.D.

Goals of the Advisory Subcommittee:

To provide expertise and feedback to ACPS, specifically in the areas of:

Exposure-Response Modeling (Pharmacometrics)

Pediatric Clinical Pharmacology

Pharmacogenetics

Past Meeting on April 22-23, 2003

Topic # 1:

Quantitative Risk Analysis Using Exposure-Response for Determining Dose Adjustment for Special Populations

Peter Lee, Ph.D.

Example 1

Nhi Nguyen, Ph.D.

Example 2

Jenny J. Zheng, Ph.D.

Example 3

He Sun., Ph.D.

Example 4: Optimizing dosing strategies for defined therapeutic targets

Mats Karlsson, Ph.D.

Topic # 2

Pediatric Population Pharmacokinetics (PPK) Study Design Template and Analyses of the FDA Pediatric Database

Lawrence Lesko, Ph.D.

Pediatric PPK template

Peter Lee, Ph.D.

Pediatric Database Analysis

Gene Williams, Ph.D.

Topic # 3

Pharmacogenetics: Improvement of Existing Drug Treatments

Lawrence Lesko, Ph.D.,

Topic # 4

Drug Interactions: Metabolism and Transport-Based

Shiew-Mei Huang, Ph.D.

Next CPSC Meeting on November 17 and 18, 2003
Tentative Agenda

Topic # 1

Quantitative Analysis Using Exposure-Response: Proposal for End-of-Phase2A (EOP2A) Meeting and Use of Clinical Trial Simulation (CTS) for PK-QT Study Design

Topic #2

Pediatric Decision Tree:

Examples for Applying the Pediatric Decision Tree

Use of CTS in Pediatric Population Pharmacokinetics Study Design

Topic #3

Drug-Drug Interactions

Topic #4

Pharmacogenetics: Integration into New Drug Development

CPSC Membership

Jürgen Venitz, MD, Ph.D. (Chair)

Associate Professor, Dept. of Pharmaceutics

Virginia Commonwealth University School of Pharmacy, Richmond, VA

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Professor/Chairman, Dept. Biomedical Engineering

University of Southern California, Los Angeles, CA

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University of Florida College of Pharmacy, Gainesville, FL

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Professor and Chair, Dept. of Pharmacology

College of Medicine and Public Health, Ohio State University, Columbus, OH

Current ACPS Member