

Workshop Agenda				
Presentation Title	Time (ET)	Speaker		
Introduction				
Welcome and Introduction	10:00am-10:10am	Issam Zineh, FDA		

Session 1- Current State: Liver Disease, Hepatic Impairment and Pharmacokinetics (PK)

Moderator: Martina Sahre, FDA		
Overview of Current State of Assessment of Hepatic Impairment at FDA	10:10am-10:25am	Martina Sahre, FDA
Nature of Liver Disease & Pharmacokinetic Alterations	10:25am-10:40am	Naga Chalasani, Indiana University
Pharmacokinetics in Acute Liver Injury	10:40am-10:50am	Paul Hayashi, FDA
Challenges and Opportunities in Deriving Dosing Recommendations for Patients with Hepatic Impairment	10:50am-11:00am	Tiffany Kaiser, University of Cincinnati
Child-Pugh Score	11:00am-11:10am	Guadalupe Garcia-Tsao, Yale
MELD	11:10am- 11:20am	Patrick Kamath, Mayo Clinic
Liver Dysfunction Groups - NCI Organ Dysfunction Working Group Criteria	11:20am-11:30am	Stacy Shord, FDA
Summary and Panel Discussion	11:30am-12:00pm	Panelists: Naga Chalasani, Indiana University Lara Dimick, FDA Tiffany Kaiser, University of Cincinnati Patrick Kamath, Mayo Clinic Lupe Garcia-Tsao, Yale Stacy Shord, FDA
Lunch Break	12:00pm-12:30pm	I

Session 2- New Insights on Identification and Classification of Hepatic Impairment for the Purpose of Assessing PK Changes in Liver Disease

Session Moderator: Insook Kim, FDADMET Changes in Progressive NAFLD: Illustrations and Complexities12:30pm-12:45pmJohn Clarke, Washington State UniversitySensitive OATP Substrates and Hepatic Impairment: Firsocostat as a Case12:45pm-1:00pmCara Nelson, Gilead Sciences, IncSensitive OATP Substrates and Hepatic Impairment: Firsocostat as a Case12:45pm-1:00pmCara Nelson, Gilead Sciences, IncPharmacokinetic Phenoconversion in NASH: Potential for Diagnostic Staging1:00pm-1:15pmNathan Cherrington, University of ArizonaRelevance of Quantifying Global Liver Function and Physiology to Assessing Core and Other Liver Staging Models1:15pm-1:30pmSteve Helmke, HepQuantPharmacokinetics Context: Child-Pugh Score and Other Liver Staging Models1:30pm-1:45pmAbhay Joshi, FDASummary and Panel Discussion1:45pm-2:15pmPanelists: John Clarke, Washington State University Cara Nelson, Gilead Sciences, Inc Nathan Cherrington, University of Arizona Greg Everson, HepQuant LLC Abhay Joshi, FDABreak2:15pm-2:30pm1Session 3: Current Status of the Role of Physiologically Based Pharmacokinetic (PBPK) Modeling in Charactorizing the PK of Drugs in Hepatic Impairment1Moderator: Xinyuan (Susie) Zhang, FDA and Copressions: Challenges and Oportunities2:30pm-2:45pmYing-Hong Wang, FDAModerator: Xinyuan (Susie) Zhang, FDA in Regulatory Subpost Dosing Recommendations for Patients with Hepatic Impairment2:45pm-3:00pmStephen D. Hall, Eli Lilly and Co Viera Lukacova, Simulations Plus, IncPBPK modeling to predict PK in patients with liver impairm		Assessing PR Changes in Liver Disease				
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