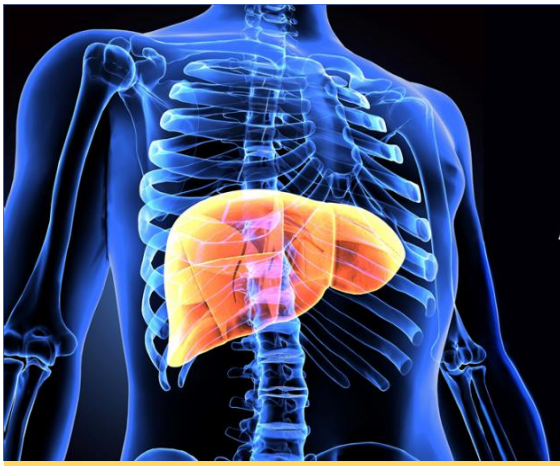

Food and Drug Administration (FDA) and Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI) Public Workshop:

Assessing Changes in Pharmacokinetics of Drugs in Liver Disease

October 8, 2020
10:00 AM to 4:00 PM
Virtual Workshop

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**	

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, FDA		
DMET Changes in Progressive NAFLD: Illustrations and Complexities	12:30pm-12:45pm	John Clarke, Washington State University
Sensitive OATP Substrates and Hepatic Impairment: Firsocostat as a Case Example	12:45pm-1:00pm	Cara Nelson, Gilead Sciences, Inc
Pharmacokinetic Phenoconversion in NASH: Potential for Diagnostic Staging	1:00pm-1:15pm	Nathan Cherrington, University of Arizona
Relevance of Quantifying Global Liver Function and Physiology to Assessing Changes in PK of Drugs in Liver Disease	1:15pm-1:30pm	Steve Helmke, HepQuant
Hepatic Impairment Classifications from a Pharmacokinetics Context: Child-Pugh Score and Other Liver Staging Models	1:30pm-1:45pm	Abhay Joshi, FDA
Summary and Panel Discussion	1:45pm-2:15pm	**Panelists:** John Clarke, Washington State University Cara Nelson, Gilead Sciences, Inc Nathan Cherrington, University of Arizona Greg Everson, HepQuant LLC Abhay Joshi, FDA Mark Avigan, FDA
Break	**2:15pm-2:30pm**	
Session 3- Current Status of the Role of Physiologically Based Pharmacokinetic (PBPK) Modeling in Characterizing the PK of Drugs in Hepatic Impairment		
Moderator: Xinyuan (Susie) Zhang, FDA		
Applications of Hepatic Impairment PBPK in Regulatory Submissions: Challenges and Opportunities	2:30pm-2:45pm	Ying-Hong Wang, FDA
Physiologically Based Pharmacokinetic Modeling to Support Dosing Recommendations for Patients with Hepatic Impairment: A Readout from the IQ Consortium	2:45pm-3:00pm	Stephen D. Hall, Eli Lilly and Co
PBPK modeling to predict PK in patients with liver impairment	3:00pm-3:15pm	Viera Lukacova, Simulations Plus, Inc
Summary and Panel Discussion	3:15pm-3:45pm	**Panelists:** Ying-Hong Wang, FDA Stephen D. Hall, Eli Lilly and Co Viera Lukacova, Simulations Plus, Inc
Closing Remarks		
Summary & Future Steps	3:45pm-4:00pm	Joga Gobburu, University of Maryland