KIDNEY HEALTH INITIATIVE

Standardized Pharmacokinetic Assessment in Patients Receiving Continuous Renal Replacement Therapy

November 11, 2014 • Pennsylvania Convention Center

Open Workshop to Present Recommendations from the KHI Project

Identifying workable approaches to address the paucity of data to inform the dosing of certain drugs given in the context of critical illness and CRRT has significant life-saving potential. A KHI workgroup has proposed possible pragmatic solutions to conducting studies in the setting of CRRT that would generate informative PK data. Meeting attendees will include representatives from FDA, the pharmaceutical industry, pharmacologists, nephrologists, and other affected stakeholders. Broad participation is desired to ensure that the strengths and limitations of the KHI workgroup recommendations are elucidated.

View the white paper that has been electronically published by the *Clinical Journal of American Society of Nephrology*

Tuesday, November 11, 2014 *Program Subject to Change*

10:00 AM	**Registration Opens**
10:30 AM	**Welcome Remarks** *Patrick Archdeacon, MD, US Food and Drug Administration and Kidney Health Initiative Co-Chair and* *Thomas D. Nolin, PharmD, PhD, FASN, Assistant Professor, Pharmacy and Therapeutics, University of Pittsburgh and Kidney Health Initiative Workgroup Chair*
10:45 AM	**Pharmacokinetics Studies in Continuous Renal Replacement Therapy (CRRT): An Introduction** Clinical Needs and Options: FDA Perspective *Alan Shapiro, MD, PhD, FDA Office of Antimicrobial Products (OAP)* *Mayurika Ghosh, MD, FDA Office of Antimicrobial Products (OAP)*
11:00 AM	Pharmacokinetics Studies in CRRT: Necessity, Experience and Opportunity *Stuart Goldstein, MD, Director of the Center for Acute Care Nephrology at Cincinnati Children's Hospital Medical Center*
11:15 AM	When is a Pharmacokinetic Study in CRRT Warranted? *William H. Fissell, MD, Associate Professor, Nephrology and Hypertension, Vanderbilt University*
11:30 AM	Study Design Considerations In Vivo Studies in Humans on CRRT *Thomas D. Nolin, PharmD, PhD, FASN*
11:45 AM	Study Design Considerations: FDA Perspective *Rajnikanth Madabushi, PhD, Team Leader, Cardio Renal, FDA Office of Clinical Pharmacology (OCP)*
12:00 PM	**Lunch Break**
1:00 PM	Panel Discussion of Morning Sessions *Co-moderators: Stuart Goldstein, MD and Shiew Mei Huang, PhD, Deputy Director, FDA Office of Clinical Pharmacology* *Panelists:* *George Aronoff, MD, Assistant Chief Medical Officer, Renal Ventures Management, LLC* *Barry I. Eisenstein, MD, Senior Vice President of Scientific Affairs, Cubist Pharmaceuticals* *William H. Fissell, MD* *Thomas D. Nolin, PharmD, PhD, FASN* *Rajnikanth Madabushi, PhD* *Douglas Silverstein, MD, Medical Officer, FDA Center for Devices and Radiological Health (CDRH)*

2:00 PM **Break**

Utility of Alternative Methods: In Vitro and In Silico for CRRT

2:15 PM Utility of In Vitro Approaches to Help Inform Dosing
Bruce Mueller, PharmD, FASN, Associate Dean for Academic Affairs and Professor of Pharmacy, University of Michigan

2:30 PM The New Face of PBPK: Network of Sub-Models & Their Relevance to Special Populations
Amin Rostami, PharmD, PhD, Professor of Systems Pharmacology at the Centre for Applied Research in the School of Pharmacy and Pharmaceutical Sciences at the University of Manchester

2:45 PM Future Directions: A Pharmaceutical Industry Perspective
Richard Lalonde, PharmD, Global Head of Clinical Pharmacology, Pfizer, Inc.

3:00 PM Panel Discussion
Co-moderators: Shiew Mei Huang, PhD, Deputy Director, FDA Office of Clinical Pharmacology and Joanna Hudson, PharmD, FASN, Associate Professor, University of Tennessee-Memphis College of Pharmacy
Panelists:
Michael F. Flessner, MD, PhD, Program Director, National Institute for Diabetes and Digestive and Kidney Diseases
Stuart Goldstein, MD,
Richard Lalonde, PharmD
Bruce Mueller, PharmD, FASN
Amin Rostami, PharmD, PhD
Vikram Sinha, PhD, Division of Pharmacometrics Director, FDA Office of Clinical Pharmacology (OCP)

4:00 PM **Closing Remarks**
Issam Zineh, PharmD, MPH, FCP Director, FDA Office of Clinical Pharmacology (OCP)

4:15 PM Adjourn

Registration is complimentary but required for our planning purposes.

Webcast of the workshop will be available. See registration form to denote your interest in this option. A link for the webcast will be sent closer to the meeting.

For more information:
www.kidneyhealthinitiative.org
or
Contact us: khi@asn-online.org

The workshop will coincide with ASN Kidney Week 2014 and is open to all, but is not an official part of the ASN Kidney Week 2014 program.