CRITICAL PATH INSTITUTE

View Now | International 2022 Drug-induced Kidney Injury Biomarker Workshop

On May 23-24, 2022, the Critical Path Institute hosted the *International Drug-induced Kidney Injury Biomarker Workshop.* In collaboration with key opinion leaders from academic institutions, the pharmaceutical industry, health authorities and the patient community, the two-day public virtual workshop brought together stakeholders to align on a plan for developing improved tools to predict and detect drug-induced kidney injury (DIKI). A report summarizing the workshop and next steps can be viewed here. A full playlist of all videos associated with the workshop is available, here.

View Day 1 Now

DIKI Biomarker Workshop: Day 1

May 23, 2022: 10:00 AM – 3:00 PM EST

Session 1: Defining the Challenge and Unmet Need			
Time	**Topic**	**Summary**	**Speakers**
10:00 – 10:05 AM	**Welcome**		Nicholas King
10:05 – 10:30 AM	**Stakeholder Perspectives**	Perspectives on drug safety and data sharing	Rebecca Cheung Marla Levy Aliza Thompson Frank Dieterle Matthias Kretzler
10:30 – 10:50 AM	**Understanding Drug-Induced Kidney Injury (DIKI)**	Need for improved tools to inform decision making, including workshop's focus on DIKI biomarkers	Jonathan Himmelfarb Joe Bonventre
10:50 – 11:20 AM	**Defining the Challenge of DIKI**	Defining the scope of the problem including the need for education, current inadequate tools/biomarkers, and need for data sharing	James Dear Vishal Vaidya

11:20 – 11:35 AM	**Current Landscape**	Understanding current activities and opportunities and addressing ways to collaborate to make the highest impact	Gary Friedman
11:35 – 12:35 PM	**Leveraging DIKI Biomarkers to Inform Decision Making for Phase I – III Clinical Trials**	Insights into biomarker strategy and outcomes, barriers, and challenges, preparing novel biomarkers for application in clinical trial decision making; how access to additional biomarker data would have improved study design and decision making before and after trials	Stefan Sultana Steve Piccoli Jeffrey Siegel
12:35 – 12:45 PM	**Break**		
12:45 – 1:30 PM	**Panel Discussion**		All speakers in session
Session 2: Addressing the Unmet Need Through Collaborations			
1:30 – 1:40 PM	**Personal Perspectives**	Drug safety and collaboration	Glenda Roberts
1:40 – 2:10 PM	**Addressing the Unmet Needs**	Outline and discuss an action plan framework for implementing broad DIKI biomarker use	Gary Friedman Ameeta Parekh
2:10 – 2:55 PM	**Breakout Sessions/Q&A**	Discuss what needs to be done to advance novel kidney injury biomarker application and implementation: • What breadth of demographics are needed for meaningful implementation? • What is the best way to integrate disparate data? • What type(s) of injury need to be assessed? • What can be done to enable stronger patient engagement?	Session Leaders:Stefan Sultana / Richard Knight Gary Friedman / Becca Cheung Aliza Thompson / Glenda Roberts
2:55	**Closing Comments**		Nicholas King
3:00 PM	**END OF DAY 1**		

View Day 2 Now

DIKI Biomarker Workshop: Day 2

May 24, 2022: 9:00 AM – 2:00 PM EST

Session 3: Building Solutions and Innovative Drug Development Tools			
Time	**Topic**	**Summary**	**Speakers**
9:00 – 9:10 AM	**Welcome**		Nicholas King

9:10 – 9:20 AM	**Personal Perspective**		Kevin Fowler Richard Knight
9:20 – 9:30 AM	**Breakout Session Highlights**	Summary of output from May 23 breakout sessions	Nicholas King
9:30 – 10:35 AM	**Success through Collaboration**	1. Biomarkers of drug-induced acute interstitial nephritis (AIN) 2. Glutamate dehydrogenase application to detect drug-induced liver injury 3. Kidney Precision Medicine Project (KPMP) 4. C-Path PSTC/Biomarker Data Repository 5. Data sharing generating new insights	Chirag Parikh Jiri Aubrecht Matthias Kretzler Nicholas King Yemi Adedeji
10:35 – 11:05 AM	**Panel Discussion**		All speakers in session
11:05 – 11:35 AM	**Breakout Sessions**	Discuss implementation of an action plan to advance novel kidney injury biomarker application: 1. What breadth of demographics are needed for meaningful implementation? 2. What is the best way to integrate disparate data? 3. What type(s) of injury need to be assessed? 4. What can be done to enable stronger patient engagement?	Session Leaders:Stefan Sultana / Richard Knight Gary Friedman / Glenda Roberts Aliza Thompson / Kevin Fowler
11:35 – 11:45 AM	**BREAK**		
11:45 – 12:15 PM	**Overcoming Barriers to Data Sharing: Why and How**		Amanda Borens
12:15 – 12:35 PM	**Data Sharing for Solutions**	1. FDA perspective on data sharing 2. Industry perspective on data sharing	Christine Garnett Shashi Ramaiah
12:35 – 1:30 PM	**Panel Discussion**		All speakers in session and Glenda Roberts, Rob Star, Mike Pacanowski, Ray Harris

1:30 – 1:50 PM	**A Collaboration to Address the Action Plan**	Present proposal for next steps as a consortium/collaboration	Nicholas King
1:50 PM	**END OF WORKSHOP**		