Draft Agenda

Workshop: BioMed21 – A Human Pathways Approach to Disease Research

Co-organized by the National Toxicology Program and the Human Toxicology Project Consortium

Fishers Lane Conference Center
National Institutes of Health
Bethesda, MD
June 26-27, 2017

Monday, June 26

Time	Agenda Item	Presenter
8:00 a.m.	**Registration and continental breakfast outside meeting room** *Refreshments sponsored by the Human Toxicology Project Consortium*	
8:30 a.m.	**Welcome, summary of workshop, goals, work products**	Kate Willett Humane Society of the United States (HSUS)/Humane Society International (HSI)
8:45 a.m.	**Keynote Lecture – A Call to Action**	Chris Austin National Center for Advancing Translational Sciences (NCATS)
9:30 a.m.	**Session 1 – Setting the Stage: What is Needed and Why?**	Chair: Warren Casey National Institute of Environmental Health Sciences (NIEHS)
9:35 a.m.	• **Challenges and needs to use existing data in drug development**	François Pognan Novartis
9:55 a.m.	• **A strategic roadmap to the implementation of alternatives**	Warren Casey NIEHS
10:20 a.m.	• **Clinical point of view: current practices, challenges, and needs**	Bruce Cuthbert National Institute of Mental Health
10:45 a.m.	**Break** *Refreshments sponsored by the Human Toxicology Project Consortium*	
11:00 a.m.	• **FDA collaborations for addressing practical applications**	Suzanne Fitzpatrick Food and Drug Administration (FDA)
11:20 a.m.	• **Case studies in 21st century disease models** ◦ A tiered approach to in vitro-based compound testing: Using computational modeling, big data approaches and fit-for-purpose in vitro assays to streamline compound development ◦ Using organoids to define key pathways in chronic obstructive pulmonary disease (COPD) pathogenesis ◦ Organs-on-chips: A platform for advancing drug development and disease modeling	Rebecca Clewell ScitoVation Ian Adcock Imperial College London Daniel Levner Emulate, Inc.
12:30 p.m.	**Lunch (on your own)**	

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Monday, June 26 (*continued*)

Time	Agenda Item	Presenter
1:45 p.m.	**Breakout Group Discussion Session 1**	
2:45 p.m.	**Break** *Refreshments sponsored by the Human Toxicology Project Consortium*	
3:00 p.m.	**Session 2 – Big Data; Information Into Knowledge Into Action**	Chair: Ajay Pilli Library of Integrated Network-based Cellular Signatures (LINCS) Program, National Institutes of Health (NIH)
3:10 p.m.	• **Overview of NIH big data projects, LINCS in particular**	Ajay Pilli NIH LINCS
3:30 p.m.	• **Biomedical Data Translator – What's it going to take?**	Christine Colvis NIH Translator
3:50 p.m.	• **Translator and Fanconi anemia**	Christopher Chute NIH Translator
4:10 p.m.	**Break** *Refreshments sponsored by the Human Toxicology Project Consortium*	
4:30 p.m.	**Breakout Group Discussion Session 2**	
5:30 p.m.	**Break** *Refreshments sponsored by the Human Toxicology Project Consortium*	
5:40 p.m.	**Recap Day 1**	
6:00 p.m.	**Adjourn**	

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Tuesday, June 27

Time	Agenda Item	Presenter
8:00 a.m.	**Registration and continental breakfast outside meeting room** *Refreshments sponsored by the Human Toxicology Project Consortium*	
8:30 a.m.	**Session 3 – Current Tools to Support Pathway-based Decisions**	Chair: Suzanne Fitzpatrick FDA
8:30 a.m.	• **Tox21 and beyond for pharma and biomed**	Anton Simeonov NCATS
8:50 a.m.	• **Organs-on-a-chip: Applications for testing and research**	Lucie Low NCATS
9:10 a.m.	• **Primary cell-based phenotypic profiling for building human outcome pathways**	Ellen Berg DiscoveRx Corporation
9:30 a.m.	• **Systems biology approach to cancer**	Shannon Hughes National Cancer Institute
9:50 a.m.	**Break** *Refreshments sponsored by the Human Toxicology Project Consortium*	
10:00 a.m.	• **How might a "pathway-based" approach help (e.g., AOPs)**	Kate Willett HSUS/HSI
10:20 a.m.	• **A network-based approach to understanding drug toxicity and its application to human liver disease**	Jeff Sutherland Consultant, Indiana Biosciences Research Institute
10:40 a.m.	• **Systems pharmacology (PredicTox)**	Darrell Abernethy FDA
11:00 a.m.	**Break** *Refreshments sponsored by the Human Toxicology Project Consortium*	
11:15 a.m.	**Breakout Group Discussion Session 3**	
12:15 p.m.	**Lunch (on your own)**	
1:15 p.m.	**Summary of Breakout Group Discussions 1-3**	

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Tuesday, June 27 (*continued*)

Time	Agenda Item	Presenter
2:45 p.m.	**Session 4 – Coordination and Support: How to Make it Work**	Chair: Troy Seidle HSI
	• **Panel discussion** ◦ Role of funding agencies ◦ Role of pharma ◦ Role of academia/SMEs ◦ Role of regulatory agencies	Chris Austin NCATS François Pognan Novartis Daniel Levner Emulate Frank Weichold FDA
3:45 p.m.	**Break** *Refreshments sponsored by the Human Toxicology Project Consortium*	
4:00 p.m.	**Group Discussion Session 4**	
4:40 p.m.	**Break** *Refreshments sponsored by the Human Toxicology Project Consortium*	
4:50 p.m.	**Wrap-up: Summary of Discussion Questions**	Chairs: Warren Casey NIEHS Kate Willett HSUS/HSI
5:00 p.m.	**Adjourn**	