



**The Second International Transporter Consortium Workshop (ITCW2)**  
“Membrane Transporters in Drug Development: Best Practices and Future Directions”  
*Gaylord National Convention Center, National Harbor, Maryland, USA, March 12-13, 2012*

Dear JSSX Colleague:

The Second International Transporter Consortium Workshop (ITCW2), “Membrane Transporters in Drug Development: Best Practices and Future Directions” will take place at the Gaylord National Convention Center (10min from Washington DC) on Mon/Tues March 12/13, 2012 as part of the ASCPT annual conference. We have strived to compile a highly relevant program with a robust line-up of international scientific experts from industry, academia, and government. Please refer to the following web site: <http://www.ascpt.org/2012AnnualMeeting/ScientificPreconferences/InternationalTransporterConsortiumWorkshopTwo/tabid/8208/Default.aspx>

This workshop will continue the themes of the first ITC workshop, as captured in the associated white paper (Nature Reviews Drug Discovery 9, 215-236 (2010)) which was the most cited publication of NRDD in 2010 (cf commentary in NRDD 11, p3 (2012)). The white paper fostered constructive dialog between academia, industry and regulators which helped to provide perspectives for the FDA draft DDI guidance. There will be an opportunity to hear first hand from the FDA as well as the EMA at this workshop. The second workshop aims to continue the ongoing discussion with sessions on emerging transporters (MATEs, MRP2, BSEP), expanding on in vitro and in vivo techniques (MALDI, cell systems), and highlighting the importance of considering intracellular concentrations, transporter kinetics, and PBPK when evaluating drug transport. There will also be an update from the digoxin/Pgp IC50 Pharma working group. The workshop will devote the final afternoon to presentations and discussions on regulatory and industry perspectives highlighting the impact of the white paper and regulatory guidances in drug development.

This is your opportunity to hear first hand relevant transporter related issues from your colleagues in industry, academia and regulatory authorities and to provide your insights and feedback on the white paper and guidances. We hope that the workshop will build on the dialog stimulated by the first workshop, solidify our current understanding, challenge our current thinking, and prepare us for the future so that we can better address those complex and important issues related to Drug Transporters. It is our intent to compile additional white papers based on these discussions.

There will also be 5 breakout sessions on relevant topics where there will be an opportunity for you to voice your opinion and contribute to our current understanding of these topics.

We also invite you to join us on Tuesday, March 13, 2012, 5:00 pm – 6:00 pm for a conversation on moving the ITC forward. This is your opportunity to provide input to the group as we plan for the future.

The ITCW2 Organizing Committee

Donald Tweedie (Chair), Kim Brouwer, Kate Hillgren, Keith Hoffmaster, Toshi Ishikawa, Dietrich Kepler, Maciej Zamek-Glisczynski, Lei Zhang.



## The Second International Transporter Consortium Workshop (ITCW2)

### Program

	Monday March 12th	Chairs/Speakers
7:30 – 8:30	Registration	
8:15 – 8:30	Introductory Remarks	Donald Tweedie
	Session I: Transport Pharmacokinetics	Maciej Zamek-Glisczynski, Ping Zhao, Toshi Ishikawa
	Part I: In Vitro Kinetics and Extrapolation Methods	
8:30 – 8:55	Proper Estimation of Basic Transport Parameters In Vitro. Calculation of Km and Ki in Monolayers: Reconciling In Vitro Parameters with In Vivo and Clinical PK.	J. Cory Kalvass, Abbott
8:55 – 9:20	Proper Estimation of Basic Transport Parameters In Vitro. PhRMA IC50 Working Group Recommendations.	Caroline Lee, Consultant
9:20 – 9:45	Preclinical to Clinical Extrapolation of Transport Kinetics. Fraction Excreted, RAF, and REF.	Maciej Zamek-Glisczynski, Eli Lilly
9:45 – 10:15	Break	
	Part II: Incorporation of Transport into PBPK models for PK and DDI Predictions.	
10:15 – 10:50	Incorporation of Transport into PBPK Models	Masoud Jamei, SimCYP
10:50 – 11:25	Evaluating Transport and Metabolism Interplay using PBPK Models	Aleksandra Galetin, University of Manchester
11:25 – 12:00	Q&A Panel Discussion	
12:00 – 1:00	Lunch	
	Session 2: Tools to Study Drug Transporters	Kim Brouwer, Keith Hoffmaster
1:00 – 1:40	Application of MALDI Imaging Mass Spectrometry to Assess Drug Tissue Distributions and Clearance	Stephen Castellino GSK
1:40 – 1:50	Q&A	
1:50 – 2:20	<i>In Vivo</i> Methods to Assess Intestinal and Hepatobiliary Transporter-Mediated Drug-Drug Interactions	Hans Lennernäs Uppsala University
2:20 – 2:30	Q&A	
2:30 – 3:00	Break	
3:00 – 3:30	Novel Long-Term Liver Tissue Culture Approaches that Maintain Transporter Function	Nandita Shangari, Novartis
3:30 – 3:40	Q&A	
3:40 – 4:10	Novel Methods for Transport and Metabolism Assessment: Current Status and Future Directions	Tommy Andersson AstraZeneca
4:10 – 4:20	Q&A	
4:20 – 5:00	Intracellular Concentrations of Drugs/Metabolites: Measurement, Interpretation and Implications - with audience discussion	Joe Polli, Xiaoyan Chu, Kim Brouwer
5:00 – 6:00	Breakout Sessions	
6:00 – 7:30	ITC Organization/Networking/Cocktails	

	Tuesday March 13th	
8:30 – 12:00	Session 3: Additional Emerging Transporters.	Kate Hillgren, Dietrich Keppler, Lei Zhang
8:30 – 8:35	Introduction and Overview of the Session	Lei Zhang, FDA
8:35 – 9:15	Organic Cation Transport: MATEs	Kathy Giacomini, UCSF
9:15 – 9:55	Drug and conjugate efflux pumps of the ABCB family (MRP2, other MRPs)	Dietrich Keppler, Heidelberg
9:55 – 10:35	Bile acid efflux pump (ABCB11)	Bruno Stieger, Zürich
10:35 – 10:50	Break	
10:50 – 11:40	Case examples on other transporters	
10:50 – 11:15	PEPT1 and prodrug – Industry example	Kate Hillgren, Eli Lilly
11:15 – 11:40	Nucleoside transporter (hENT1) and Cancer Therapy	Carol Cass, University of Alberta
11:40 – 12:00	Q&A Panel Discussion	
12:00 – 1:00	Lunch	
1:00 – 4:00	Session 4: Decision Trees and Regulatory Issues.	Shiew Mei Huang, Donald Tweedie
1:00 – 1:30	Pharma Perspective	Joe Polli, GSK
1:30 – 1:50	FDA Perspective	Shiew Mei Huang
1:50 – 2:10	EMA Perspective	Eva Gil Bergland
2:10 – 2:30	Case Study 1: FDA	Lei Zhang, FDA
2:30 – 3:00	Break	
3:00 – 3:15	Case Study 2: Pharma	Pharma
3:15 – 3:30	Case Study 3: Pharma	Pharma
3:30 – 3:45	Case Study 4: Pharma	Pharma
3:45 – 4:00	Case Study 5: Pharma	Pharma
4:00 – 5:00	Open Discussion	
5:00 – 6:00	ITC Administrative Meeting: Organization of the ITC moving forward	Kathy Giacomini, Shiew Mei Huang, Donald Tweedie

#### Breakout Sessions:

	Breakout Session Topic	Discussion Leaders
1.	Methods: Vesicle transport and Sandwich-cultured hepatocytes to assess intracellular concentrations.	Kim Brouwer
2.	Kinetics of Transport Processes	Joe Benz, Cory Kalvass
3.	Pharmacogenomics including substrate specificity differences among OATPs	Richard Kim, Kathy Giacomini
4.	Blood Brain Barrier	Jash Unadkat
5.	Induction and regulation of transporters and changes in transporter expression/function in disease states	Joe Ware, Lei Zhang, Liangfu Chen, Toshi Ishikawa