Institute for Scientific Communications

DDI-2018

21st International Conference on Drug-Drug Interactions:

Regulatory Issues; Literature and NDA Review; In Vitro In Vivo Correlations; Physiologically-based Modeling to Support DDI Risk Assessment; Unresolved Issues and Novel Technologies for DDI Evaluation

June 14 – 16, 2018

Husky Union Building, University of Washington; Seattle, WA, USA
4001 NE Stevens Way, Seattle, WA 98195
(206) 543-8191

REGISTRATION DISCOUNT UNTIL MAY 14, 2018

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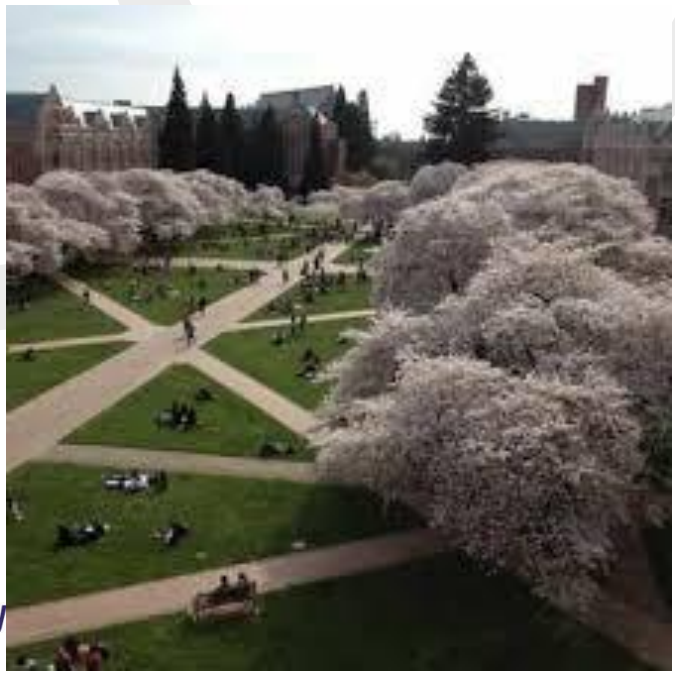

DDI-2018 MEDIA PARTNER

Featuring the Following Experts: Albert P. Li; Ken Thummel; Leslie Benet; Brian Houston; Yuichi Sugiyama; Jashvant Unadkat; Niresh Hariparsad; Jan Wahlstrom; Nina Isoherranen; Yurong Lai; Nagendra Chemuturi; Odette Fahmi; Brian Ogilvie; Sophie Argon; Savannah McFeely; Jingjing Yu; Mathena Varma; Ian Templeton; Rob Elsby; Brian Houston; Xiaoyan Chu.

DDI-2018 is a yearly event providing a comprehensive update on the status of the science of drug-drug interactions and its relevance to drug development. The conference will include a review on the current status of DDI potential of biologics, industrial perspectives and other relevant topics.

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Organizing Chairs:
Albert P. Li, APSciences/In Vitro ADMET Laboratories, Inc.
Jashvant Unadkat, University of Washington
Jingjing Yu, University of Washington
Jan Wahlstrom, Amgen Inc.

DDI-2018
21th International Conference on Drug-Drug Interactions

THURSDAY, JUNE 14, 2018
DDI-2018 – DAY 1

7:00 AM – 8:00 AM – REGISTRATION

8:00 AM – 8:15 AM
Welcome Remarks: Albert P. Li, APSciences/IVAL

8:15 AM – 8:45 AM
Opening Remarks ***(Ken Thummel, University of Washington; Seattle, WA)***

Session 1: Regulatory Issues (Chair: Jash Unadkat)

8:45 AM – 8:50 AM EXHIBITOR PRESENTATION

8:50 AM – 9:20 AM
Current International and US FDA Guidelines for In Vitro Drug-drug Interaction Evaluation ***(Odette Fahmi, DDI-Edge Consulting LLC; Shelton, CT)*** Drug-drug interactions (DDI) may be caused by CYP inhibition, CYP induction, and/or drug transporter interactions. CYP induction results in increases of drug metabolizing enzyme activities potentially leading to decreased drug efficacy and/or increased drug toxicity. As such, in vitro model systems that can rapidly and accurately determine whether potential therapeutics induce CYP3A levels are highly desirable tools for drug discovery. A review of the current effort to assess predictive DDI models considering the new FDA regulatory guidance will be discussed.

9:20 AM – 9:50 AM
Comparison between the New US FDA and Japan PMDA In Vitro DDI Guidance: Are we Close to Harmonization? ***(Brian Ogilvie, Sekisui Xenotech; Kansas City, KS)*** In September, 2017, the Japan PMDA revised its 2014 guideline and released it (only in Japanese) for comments. In October, 2017, the US FDA revised and split its 2012 draft guidance for industry on *in vitro* drug-drug interaction (DDI) studies, into one document for *in vitro* DDI studies, and another for clinical DDI studies. Dr. Brian Ogilvie, Sekisui XenoTech, will offer perspectives on major changes and differences between the two agencies' *in vitro* guidance documents, and how to harmonize your drug development strategies to meet the expectations of both.

9:50 AM – 10:20 AM – BREAK

10:20 AM – 10:25 AM – EXHIBITOR PRESENTATION

10:25 AM – 10:55 AM
ITC White Papers on Transporters and Challenges Ahead on Transporter Research ***(Jash Unadkat, University of Washington; Seattle, WA)*** The International Transporter Consortium (ITC) held a meeting in Washington DC (March 13-14, 2017) to review and update information on transporters important in drug development and DDI studies. I will update the audience on the critical take home messages of this conference and add my perspective on key challenges facing transporter research in drug development and research.

10:55 AM – 11:25 AM - SESSION 1 PANEL DISCUSSION

11:25 AM – 1:30 PM – LUNCH

Session 2: Literature and NDA Review (Chair: Jingjing Yu)

1:30 PM – 1:35 PM – EXHIBITOR PRESENTATION

1:35 PM – 2:05 PM
Review of the 2017-2018 Literature on Drug Interactions ***(Sophie Argon, University of Washington; Seattle, WA)*** "Critical Review of the literature": Last year drug-drug interactions publications will be reviewed and analyzed with focus on new discoveries on drug-enzymes, drug-transporter, and clinically noteworthy drug-drug-interactions. A case study involving the interplay of pharmacogenetic and drug interactions, highlighting the complexity of predicting potential DDI in clinical setting will also be presented.

2:05 PM – 2:35 PM
Clinical Relevance of OATP1B Inhibition: A Comprehensive Review of Preclinical and Clinical Drug Interaction Data ***(Savannah McFeely, University of Washington; Seattle, WA)*** In recent years, the impact of the OATP1B transporters on drug-drug interactions (DDIs) has become a focus of research, and the evaluation of their role in drug disposition is recommended by regulatory agencies worldwide. While sensitive substrates and inhibitors of OATP1B1/1B3 have been identified in the literature and probe drugs have been proposed by some regulatory agencies, there is no general consensus on the ideal compounds to be used for clinical DDI studies. The aim of our work was twofold: to provide a thorough analysis of the available in vitro and in vivo data regarding OATP1B1/1B3 substrates and inhibitors and, from the identified compounds, propose the most sensitive and selective as potential probes and inhibitors for clinical studies.

3:05 PM – 3:35 PM
What Can Be Learned from Recent NDAs? Key Findings on Drug Interactions for Drugs Approved by the FDA in 2017 ***(Jingjing Yu, University of Washington; Seattle, WA)*** This presentation will give a brief review on enzyme- and transporter-mediated drug interaction data for drugs approved by the FDA in 2017. Key findings from both in vitro and clinical pharmacokinetic-based drug interaction evaluations from New Drug Application reviews will be discussed.

3:35 PM – 4:05 PM – BREAK

4:05 PM – 4:35 PM
Transporters and Antibody Drug Conjugates: A Fresh Perspective ***(Nagendra Chemuturi, Novartis; Cambridge, MA)***

4:35 PM – 5:05 PM – SESSION 2 PANEL DISCUSSION

END OF DAY 1

FRIDAY, JUNE 15, 2018
DDI-2018 - Day 2

7:00 AM – 8:00 AM – REGISTRATION

Session 3: In Vitro In Vivo Correlations (Chair: Manthena Varma)

8:00 AM – 8:05 AM – EXHIBITOR PRESENTATION

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8:05 AM – 8:35 AM
The Universally Unrecognized Assumption in Predicting Drug Clearance and Organ Extraction Ratio ***(Les Benet, UCSF; San Francisco, CA)*** For almost a half-century clearance concepts have been utilized in pharmacokinetics to understand the relationship between the dose administered and the time course of systemic concentrations to predict efficacy and safety, as well as how dosing should be modified in disease states. Various models of organ clearance/elimination have been proposed and tested. The theoretical basis for the analysis of data testing these models is presented for the first time. Here we show that in vivo data collection limitations and the assumption that clearance may defined as the product of organ blood flow and the extraction ratio are only consistent with the well-stirred model of hepatic elimination. Evaluating measures of drug concentration entering and leaving an organ will appear to best fit the well-stirred model. New data re-evaluating the diazepam extraction ratio as a function of changing protein binding and response to counter arguments to this proposal will also be presented.

8:35 AM – 9:05 AM
Extended Clearance Classification system (ECCS) informed Transporter-mediated Clearance and Drug-Drug Interactions ***(Manthena Varma, Pfizer; Groton, CT)*** Membrane transporters play an important role in the absorption, distribution, clearance and elimination (ADCE) of the drugs. Supported by the pharmacokinetics data in human, several transporters including organic anion transporting polypeptide (OATP)1B1, OATP1B3, organic anion transporter (OAT)1, OAT3, organic cation transporter (OCT)2, multidrug and toxin extrusion proteins (MATEs), P-glycoprotein and breast cancer resistance protein (BCRP) are suggested to be of clinical relevance. An early understanding of transporters role in the drug disposition and clearance allows reliable prediction/evaluation of the pharmacokinetic changes due to drug-drug interactions (DDIs) or genetic polymorphisms. We recently proposed extended clearance classification system (ECCS) based on simple drug properties (i.e., ionization permeability and molecular weight) to predict predominant clearance mechanism. According to this framework, systemic clearance of class 1B and 3B drugs is likely determined by the OATP-mediated hepatic uptake. Class 3A, 4 and certain class 3B drugs are predominantly cleared by renal, wherein, OAT1, OAT3, OCT2 and MATEs could contribute to their active renal secretion. Intestinal efflux and uptake transporters largely influence the oral pharmacokinetics of class 3A, 3B and 4 drugs. Additionally, role of other transporters such as OAT2 and OCT1 in hepatic clearance is emerging. The presentation will discuss the paradigm of applying ECCS framework in mapping the role of clinically relevant drug transporters in early discovery and development; and thereby, implementing the right strategy to allow optimization of drug exposure and evaluation of clinical risk due to DDIs and pharmacogenomics.

9:05 AM – 9:35 AM
Prediction of In Vivo Hepatic Clearance of OATP Substrates: A comparison of Different IVIVE Approaches. ***(Yuichi Sugiyama; RIKEN Baton Zone Program, RIKEN Cluster for Science, Technology and Innovation Hub, RIKEN; Yokohama, Japan)*** For substrates of both OATP1Bs and CYPs, the use of the conventional in vitro-in vivo extrapolation (IVIVE) method was found to underestimate their hepatic intrinsic clearance (CLint,all). The extended clearance concept was applied during IVIVE processes and albumin was added to metabolic studies using human liver microsomes, to minimize the impact of endogenous inhibitors on kinetic parameters for CYP2C-mediated metabolism and also added to uptake studies using human hepatocytes, though mechanism is different. Our current approach offers an improvement in the prediction of CLint,all and further investigations are warranted to enhance the prediction accuracy of IVIVE. Recent reports provided quantitative predictions for OATP-mediated DDIs between statins and cyclosporine A(CsA)/rifampicin(RIF) based on PBPK models. In the process of the analyses, the in vitro–in vivo discrepancies in the Ki values for OATPs were suggested. Such discrepancies may hamper the practical use of PBPK modeling for DDI prediction via a bottom-up approach, in which model parameters are determined by scaling up in vitro experimental results. Therefore, optimization of pharmacokinetic parameters of several drugs to account for the clinical data (providing in vivo parameters) will improve the accuracy of a global in vitro-in vivo extrapolation (IVIVE) methodology. Taking a top-down approach, the present study aimed to construct a widely applicable method for optimizing PBPK model parameters that describe adequately the clinically observed interactions between statins and CsA/RIF, which were primarily caused by the inhibition of hepatic OATPs.

9:35 AM – 10:05 AM – BREAK

10:05 AM – 11:05 AM – SESSION 3 PANEL DISCUSSION

11:05 AM – 1:00 PM – LUNCH BREAK

Session 4: Physiologically-based Modeling to Support DDI Risk Assessment (Chair: Jan Wahlstrom)

1:00 PM – 1:05 PM – EXHIBITOR PRESENTATION

1:05 PM – 1:35 PM

Physiologically-based Pharmacokinetic Modelling to Investigate Transporter Mediated Drug–drug Interactions *(Sibylle Neuhoff, Certara UK Limited; Sheffield UK)* In vitro-in vivo extrapolation (IVIVE) techniques linked within a PBPK modelling framework allow quantitative predictions of metabolism enzyme-mediated and transporter-mediated DDIs. While PBPK modelling has gained reasonable acceptance with the regulatory authorities for the CYP-mediated DDIs; the predictive performances of PBPK models for the transporter-mediated DDIs have not been as widely recognised. This is partly due to the fact that some transporters require refined models in order to account for their specific translation between abundance, function and activity, while for others simpler models are sufficient for their IVIVE. I will provide an overview for which transporter (organ) IVIVE-PBPK models were successful and where further research will be required (e.g. multiple-binding sites of OATPs, electrochemical gradient-driven transport and role of endogenous compounds for transporter activity).

1:35 PM – 2:05 PM

Physiologically Based Pharmacokinetic Modeling of Transporter-Mediated Hepatic Clearance and Liver Partitioning of OATP and OCT Substrates *(Yurong Lai, Gilead)*

2:05 PM – 2:35 PM

Prediction of Metabolite-mediated DDIs using PBPK *(Ian Templeton, Genentech; South San Francisco, CA)* Generally, the parent drug is the only or primary perpetrator species responsible for the observed DDI. However, the potential contribution of metabolite(s) circulating at high levels in the blood has been recently debated. To further assess the quantitative contribution of circulating metabolite(s) to drug-drug interactions, mechanistic modeling approaches were used to predict and/or rationalize the role of circulating metabolites in observed clinical DDIs. Based on the learnings from these examples, pragmatic guidance is proposed for implementing PBPK modeling to facilitate decision making at different stages of development.

2:35 PM – 3:05 PM – BREAK

3:05 PM – 3:10 PM – EXHIBITOR PRESENTATION

3:10 PM – 3:40 PM

Strategies for Developing and Validating PBPK Models for Extrapolation to Unstudied Population *(Nina Isoherranen, University of Washington; Seattle, WA)* Physiologically based pharmacokinetic (PBPK) models have become commonplace in drug development and regulatory reviews and in academic research. With the extensive use of PBPK models, the question of when and based on what criteria a model is sufficiently validated to extrapolate to unstudied populations has become critical. The WHO has published recommendations for best practises for PBPK modeling, but no formal guidance currently exists on what are critical model acceptance criteria to expand PBPK models beyond previously studied populations. This presentation will discuss the criteria currently used to assess model performance and to validate PBPK models, and the specific considerations for each of these criteria. An objective model performance criteria used to extrapolate PBPK drug models to special populations will be covered through examples of PBPK models for selected drugs. The examples will highlight the level of reasonable expectations of PBPK modeling in specific patient groups and with available clinical data. A workflow for PBPK model development, verification and validation will be presented using the model drugs.

3:40 PM – 4:10 PM

Predicting DDIs for non-CYP enzymes *(Jan Wahlstrom, Amgen, Thousand Oaks, CA)* Quantitative prediction of the magnitude of drug-drug interactions (DDI) is critical to underwriting patient safety in the clinical setting. Key mechanistic information can help to inform physiologically-based modeling and enable reasonable predictions of DDI magnitude. Non-CYP enzymes pose additional challenges for DDI prediction, as lack of fundamental physiological inputs and sparse clinical study results may be available for model validation. This presentation will focus on integrating in vitro, preclinical and clinical data to develop quantitative predictions for DDIs due to non-CYP enzymes

4:10 PM – 4:40 PM – SESSION 4 PANEL DISCUSSION

END OF DAY 2

SATURDAY, JUNE 16, 2018
DDI-2018 - Day 3

7:00 AM – 8:00 AM – REGISTRATION

Session 5: Unresolved Issues and Novel Technologies for DDI Evaluation (Chair: Albert P. Li)

8:00 AM – 8:05 AM – EXHIBITOR PRESENTATION

8:05 AM – 8:35 AM

Transporter Drug-Drug Interactions: An Evaluation of Approaches and Methodologies *(Rob Elsby, Evotec; Cheshire, UK)* Quantitative prediction of drug-drug interactions (DDI) from in vitro data is used to assist with clinical protocol design and towards reducing unexpected clinical findings later in drug development. However, a key challenge in DDI prediction is the differences between reported models. This talk focusses on four recent influential publications on transporter DDI prediction using static models which evaluate

interactions with individual transporters and in combination with other drug transporters and drug metabolising enzymes, and compares and contrasts how each model varies in their assumptions (including input parameters), reproducibility, complexity and application.

8:35 AM – 9:05 AM
Under Prediction of Hepatic Clearance from In Vitro Studies: Prospects for Resolution *(J Brian Houston, University of Manchester, UK)* In vitro kinetic studies designed to assess transporter- and metabolic-mediated hepatic clearance provide valuable predictions of in vivo pharmacokinetics. However quantitative predictions of clearance consistently underestimate the true in vivo value. The use of Empirical Scaling Factors (ESF) to bridge this gap is common but there is need for a scientific rationale and preferably an independent basis for assessment. Different approaches to the use of ESF for scaled hepatocyte parameters to describe both transporter- and metabolic-mediated hepatic clearance will be discussed. The feasibility of cross species scaling to achieve improved predictions will be presented.

9:05 AM – 9:35 AM
Evaluation of Endogenous Biomarkers for Transporter Inhibition: Current State and Future Considerations *(Xiaoyan Chu, Merck & Co., Rahway, NJ)* Drug transporters play a critical role in the elimination of a wide range of drugs and xenobiotics and inhibition of these transporters may cause clinically significant drug-drug interactions (DDIs). Many endogenous compounds are substrates of drug transporters. Determining the impact of perpetrator drugs on the plasma or urinary exposure of these potential endogenous biomarkers in humans is being explored as an alternative approach to assess the DDI liability of drug candidates, especially in early drug development. In this presentation, I will provide an overview of recently identified biomarkers for studying the inhibition of hepatic and renal transporters; summarize the methods and strategies employed to identify biomarkers; and discuss the utility, limitation, and future direction of biomarker approaches to predict transporter-mediated DDIs.

9:35 AM – 10:05 AM – BREAK

10:05 AM – 10:10 AM – EXHIBITOR PRESENTATION

OPTIVIA BIOTECHNOLOGY

10:10 AM – 10:40 AM
Novel Hepatocyte and Enterocyte Technologies for the Evaluation of Human Drug Metabolism, Drug-drug Interactions, and Drug Toxicity *(Albert P. Li, IVAL; Columbia, MD)* Human-based in vitro experimental systems can be applied during preclinical stages of drug development for the assessment of human-specific drug properties. In this presentation, novel human hepatocyte and enterocyte-based systems included 999Elite™ cryopreserved human hepatocytes (90% viability, >90% confluency, >9 days in culture), MetMax™ cryopreserved human hepatocytes (permeabilized, cofactor-supplemented cryopreserved human hepatocytes), cryopreserved human enterocytes, and cryopreserved human intestinal mucosal epithelium (CHIM) and their application to evaluate hepatic and enteric drug metabolism, drug-drug interactions, and drug toxicity will be discussed.

10:40 AM – 11:10 PM – SESSION 5 PANEL DISCUSSION

11:10 PM – 12:00 PM
FINAL REMARKS – Albert P. Li, IVAL

END OF DAY 3

END OF CONFERENCE

About Institute for Scientific Communications, Inc.

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POSTER PRESENTATIONS:

Poster Presentations are always encouraged. Please submit your poster abstract for approval by the organizing board by May 20th. Poster size should be no larger than 3 feet high by 6 feet long. Abstracts of posters will be included in the conference materials and will be available on the ISC website. The conference materials will be posted on the basis of availability from the author or presenter. There is no formal poster presentation scheduled. All posters will remain displayed throughout the conference. Please be prepared to display your poster during registration on Thursday, June 14th before the first session begins. Poster presenters will have ample time for discussion during breaks and Panel discussions. Submit posters abstracts for approval to Nola Mahaney, ISC; 9221 Rumsey Road, Suite # 8; Columbia, MD 21045 or email files attachment to nola@ifscomm.org. Approved poster applicants are responsible for completing a conference attendance registration form and payment of fee - visit www.ifscomm.org - and for the shipping of the poster itself. Please contact Nola Mahaney for any questions or comments. Please refer to "Travel Information" for hotel address and shipping information.

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Hotel guests have access to each property's amenities. Watertown guests may use the pool at University Inn and University Inn guests may use the fitness room and free road bikes offered at Watertown. Both hotels offer complimentary guest laundry facilities.

Conference Registration Payment
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Cancellation Policy

All cancellations are subjected to a $250.00 cancellation fee. Longer than 30 days, 100% refund (less cancellation fee). Less than 30 days, no refund but registration may be transferred to another person. All refund requests must be in writing. All refunds will be issued after the meeting has occurred. No refunds requests will be accepted after May 29, 2015. Please submit cancellation and refund requests including transferring of registration to: Fax: 410-869-9560; E-mail: nola@ifscomm.org; **Cancel Deadline: May 14, 2018**

Registration Form AVAILABLE ONLINE AT WWW.IFSCOMM.ORG Email to nola@ifscomm.org with remittance to: **ISC, Inc. 9221 Rumsey Road, Suite # 8; Columbia, MD 21045, USA; FAX No: (410) 869-9560.** Payment may be made by check in US$, payable to **Institute for Scientific Communications, Inc.** or by credit card.

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DDI-2018 Registration Fee Schedule

Event Name	Registration Fee	Registration Fee	Exhibitor Fee
	Until May 14, 2018	After May 14, 2018	
DDI-2018	$ 1,250.00	$ 1,500.00	$ 2,000.00

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