



DIA 2013 49th Annual Meeting
“Advancing Therapeutic Innovation and Regulatory Science”
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Boston, MA

Session 318 – Molecular Predictors of Drug Induced Harm: From Clinical Development to Postmarketing Surveillance

As it becomes commonplace for patients to manage their health with multiple drugs there is an increased risk for drug drug interactions (DDIs). Each year 1% of DDIs lead to adverse affects (~ 2 million cases), costing the U.S. alone \$136 billion/yr.

Session 318, *Molecular Predictors of Drug Induced Harm: From Clinical Development to Postmarketing Surveillance*, focused on pharmacovigilance with predictive models. Dr. Niklas Noren (Uppsala Monitoring Center), session chair, introduced the presenters and presentations, each describing a unique approach using *in vitro* and/or human pharmacokinetic data and highlighting opportunities and challenges in predicting and assessing DDIs.

Dr. Peter Kilford (Covance Inc.) began with highlighting the changes in European and U.S. regulation of DDI prediction, which now suggest the use of mechanistic models or *in silico* analysis. Dr. Kilford explained the importance of specific *in vitro* assays used to determine the necessity of *in vivo* DDI studies and stressed the importance that we “get an accurate prediction of these interactions as early as we can to help in the drug development process.” He then described a mechanistic model that integrates metrics of the liver and intestines and used it to demonstrate the prediction of Mibefradil’s DDI potential that more accurately reflects what is seen in the clinic.

Dr. Niels Bojunga (Molecular Health GmbH) followed with an even more integrative approach that leverages preclinical, clinical and patient specific data in the MASE (Molecular Analysis of Side Effects) System. Dr. Bojunga showed a circular diagram with connections across prescriptions, targets, pathways, metabolizing enzymes and more for a single patient – it literally drew wows from the audience. He also demonstrated the scalability of the MASE analysis through cohort studies to predict novel targets and combinations, highlighting the advantages of integrating patient safety data with broader molecular information.

Dr. Niklas Noren, session chair, then closed the session by presenting a “proof of concept” for the “possibility of going from patient safety data to knowing more about the chemical structure.” Dr. Noren described the ability to use Vigibase reports for Stevens-Johnson syndrome to identify structural commonalities in drugs listed in these accounts.

Each presentation left me with the sobering picture that each model requires complex data that is a challenge (to varying degrees) to collect, curate or create. Despite the challenges these analytics have already demonstrated immense promise to inform preclinical and clinical decisions. As we continue to devise increasingly elegant methods to connect molecular information to clinical data, the ways to interpret these connections and leverage this information seem endless - and exciting.

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