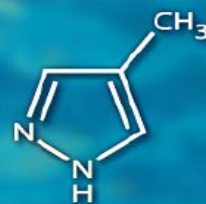


Clinical and Translational Toxicology Specialty Section



Spring 2017 Newsletter

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Message from the President

Dear Members:

It is my pleasure to welcome you at the annual SOT meeting in Baltimore, MD. I hope you will attend and enjoy clinically relevant presentations, symposia and workshops, many of them sponsored by our specialty section. It is really exciting to work in the area of clinical and translational toxicology, since our field fosters the development of new approaches, science and technologies that are directly applicable to improving drug development and/or patient care.

I hope you will enjoy this newsletter and I am looking forward to seeing you at our reception on Wednesday evening.

Jiri Aubrecht, Pharm.D., Ph.D.

The
**CTTSS Reception and
Business Meeting**
will be held on
**Wednesday, March 15th
2017**

6:00 to 7:30 pm
at the
**Hilton Baltimore
Key Ballroom 8**

6:00 – 6:30
Appetizers and Refreshments

6:30 – 6:50
Laura James, M.D.
(Keynote speaker)

6:50 – 7:30
**Business Meeting and CTTSS
Award Ceremony**

The
**CTTSS Officers
Meeting**
will be held on
**Monday, March
13th 2017**

6:30 to 8:00 am
at the
**Baltimore Convention
Center
Room 341**

We hope to see you at the reception!

This will be a great opportunity to make new acquaintances, renew old ones, and network with colleagues old and new. Feel free to invite friends and colleagues. A short business meeting will be held to report on the Specialty Section's activities in the last year, to present awards and to discuss plans for future activities.



CTTSS reception featured speaker/interview

“Clinical Validation of Toxicology Biomarkers: Importance of Experimental Design”

Dr. Laura James is a force to be reckoned with in the field of toxicology. Her research has taken her from exploring the basic mechanisms of acetaminophen-induced liver injury and subsequent regeneration to the development of a new medical device for diagnosis of acetaminophen overdose in patients. In her spare time, she has been integrally involved in pharmacokinetic studies of drugs in children, as well as synthetic cannabinoid research and surveillance. For her illustrative career bridging basic and clinical sciences, she is the recipient of the 2017 SOT Translational Impact Award.



Please summarize your professional history and current position.

I graduated from the University of South Carolina School of Medicine in 1989 and completed pediatrics residency training in 1992, followed by fellowship training in pediatric emergency medicine at the University of Alabama at Birmingham in 1994, and clinical pharmacology / toxicology training at the University of Arkansas for Medical Sciences (UAMS) and Arkansas Children’s Hospital in 1996. Over time, my focus has grown toward research and increasingly toward translational research, particularly in clinical applications of pharmacology and toxicology. I have been a faculty member of the Department of Pediatrics at UAMS since 1994. I continue to see patients at Arkansas Children’s Hospital as a clinical pharmacologist, which typically involves the management of acute poisonings or the tapering of sedation drugs in critically ill children. In 2014, I was appointed Director of the Translational Research Institute at UAMS, which houses the institution’s Clinical and Translational Sciences Award.

How did you become interested and involved in basic research? Translational research?

My interest in basic research grew from my interest in identifying better ways to diagnose and treat patients with drug toxicity, particularly acetaminophen toxicity. As a clinician, I was struck by the lack of accurate diagnostic approaches to identify drug-induced toxicity. I received a K08 award from the National Institutes of Diabetes and Digestive Diseases (NIDDK) which allowed me the time to delve into basic research that would help to “fill the gap” in the clinical management of acetaminophen toxicity patients. This award really started my interest in translational research.

You have been the main driver in the development of the point-of-care AcetaSTAT test for diagnosis of acetaminophen overdose, and your group recently published a nice validation study of the device. With positive and negative predictive values of 90-100% and 100%, respectively, the results were impressive. Can you tell us what the future looks like for the AcetaSTAT device? Where are you in the process of regulatory approval, and how soon might the device become commercially available?

As described above, AcetaSTAT performed well in a proof-of-concept study conducted in collaboration with the Acute Liver Failure Study Group. The results of this study will be published in the April issue of Clinical Gastroenterology and Hepatology. AcetaSTAT was developed through Small Business Technology Transfer (STTR) funding from the NIDDK. At this stage, Acetaminophen Toxicity Diagnostics, LLC has developed a definitive clinical protocol that is under review by the FDA to bring AcetaSTAT to market. We hope to launch the trial later this year.

Why are basic and translational research important to you? Why are they important within the field of toxicology?

I enjoy taking on new challenges and being involved in medical innovation. To move toxicology forward, multidisciplinary approaches are needed and I enjoy facilitating that work. As a clinician, I've been able to help bring the clinical perspective to the basic science laboratory. Understanding the diverse perspectives of clinicians and basic scientists and leveraging that understanding for medical innovation is where I feel I can make unique contributions. The gaps in clinical medicine are huge. Applying scientific discovery to meet the needs of patients is a driver for me.

What advances do you hope to see in translational toxicology research in the future?

Precision toxicology is where I hope we will see new growth in the future. We will be able to understand at the gene or molecular level why some individuals are more at risk for drug toxicity than others. The ability to personalize therapy to the individual will be a tremendous accomplishment. As part of this, I anticipate tremendous growth in the development and application of predictive toxicology-based biomarkers. We need to understand "early signals" that herald "risk" for the individual patient. From my viewpoint, this progress is dependent on mechanistic studies that address the etiology of drug-induced cellular injury. Understanding mechanisms will pave the way for the development of predictive toxicity-based biomarkers.

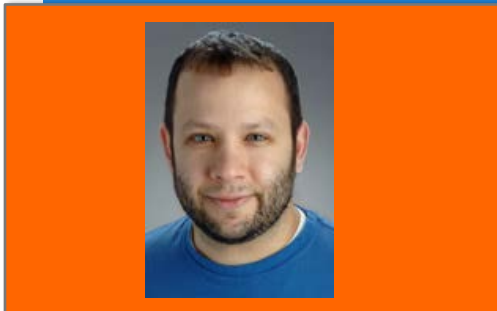
-Interview by: Mitchell McGill

**Dr. Laura James will be receiving the Translational Impact Award from SOT and as such, will be giving the Translational Impact Award Lecture: *Development of a Clinical Diagnostic Test for Acetaminophen Liver Injury*
Wednesday, March 15, 5:00 PM to 5:50
PM Convention Center Room 316**

**2017 CTTSS
Travel Award Recipient**

Congratulations to the winners!

The CTTSS is pleased to announce the winners of the section's travel award for this year, which is intended to help defray some expenses for travel of a student and/or postdoctoral fellow to present their research at the SOT annual meeting in Baltimore. The awardees will receive a recognition plaque and more importantly a check at our Section reception at the annual meeting. We hope that you are able to attend the reception to warmly greet our winners. We have provided the presentation information for our award winners below – we hope that you have time to visit their presentations and congratulate them.



Ben Woolbright, Ph.D., is currently working in the Department of Pharmacology, Toxicology & Therapeutics under the mentorship of Hartmut Jaeschke, Ph.D. at Kansas University Medical Center, Kansas City, KS.

Abstract Title: "Oncotic Necrosis Predominates Microcystin-LR-Induced Liver Injury in Primary Human Hepatocytes."

Abstract and Poster number: 2843 and P301, respectively.

Poster Presentation: Wednesday March 15, 2017 from 1:15 PM to 4:30 PM.



Mariana Cardenas-Gonzalez, Ph.D is currently working at Harvard Medical school under the mentorship of Vishal S. Vaidya, Ph.D.

Abstract Title: "Identification, Confirmation and Replication of Novel non-invasive MicroRNA Biomarkers to Detect Kidney Fibrosis in Humans"

Abstract number and Platform session: 1639, Mechanisms of Toxicity: SPC Highlights Emerging Scientists

Platform Presentation: Tuesday March 15, 2017 from 9:30 AM to 12:15 PM, Convention Center, Room 310

CTTSS-sponsored Workshops and Symposium Session

Workshops

“Cross-Industry and Regulatory Approach for the Identification and/or Qualification of Novel Safety Biomarkers of Drug-Induced Vascular Injury (DIVI),” is scheduled for **Monday, March 13, 2017, 9:30 AM to 12:15 PM** at the Baltimore

“Controversies in Pesticide Toxicology,” is scheduled for **Monday, March 13, 2017, 2:00 PM to 4:45 PM** at the Baltimore Convention Center in Ballroom IV

“Safety or Prediction? What is the Future of Regulatory Toxicity Testing,” is scheduled for **Tuesday, March 14, 2017, 2:00 PM to 4:45 PM** at the Baltimore Convention Center in Hall A

“Anesthetics, Analgesics, and Ionizing Radiation: Balancing Utility and Safety in Pregnant Women, Infants, and Children,” is scheduled for **Wednesday, March 15, 2017, 2:00 PM to 4:45 PM** at the Baltimore Convention Center in Ballroom III

Symposium Session

“Enhancing the Clinical Benefit of Cancer Drugs: Toxicity As a Therapeutic Target,” is scheduled for **Wednesday, March 15, 2017, 2:00 PM to 4:45 PM** at the Baltimore Convention Center in Ballroom I

Farewell to our outgoing officers!

Thank you for your service

Jiri Aubrecht, PharmD., PhD- President

Sally Bradberry, BSC, MD, MRCP, FAACT – Councilor

Mitchell R. McGill, PhD- Postdoctoral Representative

Corie Robinson, BS- Graduate Student Representative

We look forward to seeing you in Baltimore!

