



## Winter 2019 Newsletter

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### Announcements & Reminders:

Don't forget to [register](#) for the SOT Annual Meeting! Early-bird deadline is **January 17**. Housing reservation deadline is **February 14**.

Send in your CTTSS travel award applications! The deadline for graduate and postdoctoral CTTSS travel support is **December 31**. For more information [click here](#).



### President's Message:

**Jennifer L. Burkey, PhD**

It has been a busy year for CTTSS already, with website improvements, recruiting clinicians, review of sessions for 2020 SOT annual meeting, and keeping members posted on key dates and events. In this newsletter we feature PSTC and its contributions to translational safety biomarkers, as well as some key dates and information to keep you in the loop. Hope you all have enjoyable holidays, and we look forward to more excitement in the new year!

### Officers: 2019-2020

**President (1 year):** Jennifer L. Burkey

**Vice President (1 year):** Sally Marie Bradberry

**Vice President-Elect (1 year):** Yvonne P. Dragan

**Secretary/Treasurer (2 year):** William B. Mattes

**Past President (1 year):** John-Michael Sauer

**Councilor (2 year):** Tracy Chen

**Councilor (2 year):** Mitchell R. McGill

**Postdoctoral Representative (2 year):** Emma C. Bowers

**Student Representative (2 year):** Jephte Akakpo

## Critical Path Institute's Predictive Safety Testing Consortium 2019 Update:

The Predictive Safety Testing Consortium (PSTC) is a unique public-private partnership that brings together pharmaceutical companies to share and validate innovative translational safety testing methods under advisement of the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and Japan's Pharmaceuticals and Medical Devices Agency (PMDA). PSTC is one of several consortia comprising the Critical Path Institute (C-Path), a nonprofit organization that is dedicated to accelerating drug development by delivering on the mission outlined by the FDA's Critical Path Initiative.

The mission of PSTC is to identify new and improved translational safety testing methods for use in nonclinical and clinical studies. Many of these approaches are subsequently submitted to formal regulatory qualification.

C-Path serves as the trusted neutral third party leading the collaborative process, collecting and summarizing the data, and leading interactions with global health authorities.

In 2019 there were additional regulatory accomplishments, new publications, workshops, and industry collaborations to continue moving the science forward. A few examples include a submission to FDA by the Hepatotoxicity Working Group of a Qualification Plan for the qualification of glutamate dehydrogenase (GLDH); and a submission of a Letter of Intent by the Skeletal Muscle Injury Working Group for a safety biomarker panel to aid in the detection of acute drug-induced skeletal muscle injury.

PSTC was also successful in 2019 with completing several publications and white papers. The Nephrotoxicity Working Group, in collaboration with FNIH, published a [User's Guide for Kidney Safety Composite Measure Biomarker](#).

The Guide provides drug development companies with important information about implementing the first ever clinical safety biomarker qualified by FDA. PSTC also published a [Points to Consider Document: Scientific and Regulatory Considerations for the Analytical Validation of Assays Used in the Qualification of Biomarkers in Biological Matrices](#).

The points to consider document outlines PSTC-recommended scientific and regulatory considerations for the analytical validation of assays for fluid-based biomarkers qualified by regulatory agencies for use as DDTs.

PSTC looks forward to taking on new challenges and opportunities in 2020!

## **Calling all Clinicians!... Recruiting clinicians to the CTTSS**

interested in the impact of pharmaceuticals, chemicals, plant and fungi toxins and terrestrial and marine animal venoms on human health? Join the Clinical and Translational Toxicology Specialty Section!

The CTTSS is committed to improving the management of human poisoning by using a translational approach that links molecular mechanisms to rational therapy.

You can [\*\*join CTTSS\*\*](#) or pay membership at any time during the year through the SOT membership renewal.

If you know of colleagues that would benefit from membership in our specialty section, please let them know about us! We are the specialty section for translational science, so spread the word!

\*\*To email the Clinical and Translational Toxicology Specialty Section Leadership, please send an email to [SOTHQ@toxicology.org](mailto:SOTHQ@toxicology.org).

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## **Interested in serving as an officer in CTTSS?**

Timeline for elections:

- \* December 31, 2019 – Biosketches to SOT Headquarters
- \* January 2020 – Ballots sent from SOT Headquarters to Specialty Sections
- \* February 2020 – Ballot results sent to Specialty Sections Presidents Members

Please send our Secretary (William B. Mattes, [William.Mattes@fda.hhs.gov](mailto:William.Mattes@fda.hhs.gov)) your biosketch and the position you are interested in. Open positions and their terms this year are:

- **Vice President-Elect (1 year)**
- **Councilor (2 year)**

## Looking Ahead... SOT 2020



***Formally accepted after CTTSS endorsement: Translational science makes an impact! Look for these sessions in the upcoming program!***

We had 14 session proposals submitted to CTTSS that were endorsed by the specialty section this year, and all were formally accepted for the annual meeting in Anaheim! This includes two PSTC proposals, and 12 other proposals on a wide range of translational subjects:

- The Epidemic of Chronic Kidney Disease of Unknown Etiology in Agricultural Communities
- Aircraft Cabin Fume Events: Is There a Toxicological Explanation?
- Sex, Lungs, and Air Pollution
- Electronic Cigarettes and Cardiovascular Toxicity: New Friend or Old Foe?"
- Variety is the Life of Spice! The Clinical Toxicology of Synthetic Cannabinoids
- Parental Cannabis Exposure and Long-Term Neurobehavioral Deficits in Offspring
- Cannabidiol Science, Safety, and Societal Impacts: Where Do We stand
- Mechanisms and Multiple Exposures: Methods to Tackle Toxicology's Most Difficult Challenges Using Systematic Review Frameworks
- Using Human Genetics to Aid Safety Assessment of Therapeutics
- Quantitative and Translational Systems Toxicology: Improving Drug Safety from Pre-Clinical to Clinical Outcomes
- Express Yourself (or Not...): The Nonclinical Safety of Oligonucleotide Therapeutics
- Cyanide as a Chemical Threat: Finding Better Antidotes

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***Happy Holidays from the CTTSS!!***

