

Regulatory and Safety Evaluation

ANNUAL REPORT

May 1, 2019 to April 30, 2020

I. Officers/Committees:

<u>Officers</u>	<u>2019-2020</u>	<u>2020-2021</u>
President:	Anne Loccisano	Amy L Roe
Vice President:	Amy L Roe	Annette Koerner
Vice President-Elect:	Annette Koerner	Kristina Chadwick
Secretary/Treasurer:	Norman N Kim	Ryan Hamilton
Past President	Marie C Fortin	Anne Loccisano
Councilors:	Haitian Lu	Haitian Lu
	Ryan Hamilton	Angélique Braen
PDA Representative:	Lauren Walker	Lauren Walker
GSLC Representative:	Jessica Jimenez	Jessica Jimenez

RSESS Committees:

RSESS 2019 Scientific Program Committee: Mary Ellen Cosenza, Dave Allen, Angélique Braen, Krisa Camargo, Maggie Dempster, Ryan Hamilton, Brian Hughes, Claire Neilan, Santhini Ramasamy, and Matthew Taylor

RSESS 2020 Awards Committee: Anne Loccisano, Amy Roe, Annette Koerner, Krisa Camargo, Michael Boyle, Keith Morris-Schaffer, Miao Li, David Ackley, Sherleen Adamson, Saurabh Vispute, Ellen Baker, S. Satheesh Anand, LaRonda Morford

Ad hoc Webinar Committee: Brett Winters, Greg Smith, Marie Fortin

II. 2019 Membership total: 840

III. Activities:

2020 SOT Annual Meeting including the RSESS Reception was not held as scheduled in Anaheim, CA due to concerns regarding the coronavirus and COVID-19 pandemic.

Despite not holding an annual reception, RSESS recognized and awarded graduate students, postdoctoral scholars, and the Best Paper of the Year Award.

Regulatory & Safety Evaluation Best Paper Award Winner

Michael Dourson, Bernard Gadagbui, Chijioke Onyema, Patricia McGinnis, Ray York

“Data derived Extrapolation Factors for developmental toxicity: A preliminary research case study with perfluorooctanoate (PFOA).” Regul Toxicol Pharmacol. 2019 Nov;108:104446

RSESS Graduate Student Excellence Awards

Jennifer Schaefer, Rutgers University; “Regulation of mouse uterine aquaporin expression in the preimplantation period and the impact of ovarian superovulation.”

Luma Melo, Indiana University; “Gene expression signature of dieldrin-exposed livers in mice.”

RSESS Postdoctoral Excellence Awards

Colette Miller, US EPA; “Ozone exposure during implantation impairs offspring metabolic processes in a sex-specific manner in rats.”

Katelyn Lavrich, NIEHS; “Taking toxicology to the next dimension- evaluating the toxicological screening utility of 3D spheroid primary human hepatocyte cultures.”

RSESS “Great Debate”

The great debate was not held as the SOT meeting was cancelled.

2020 SOT Annual Meeting Courses/Sessions:

There were 114 session proposals for the 2020 SOT Annual meeting, of which 37 asked for RSESS endorsement. Ten asked for primary endorsement from RSESS and nineteen and eight asked for secondary and tertiary endorsement, respectively.

Overall, there were endorsement requests for sixteen workshops, thirteen symposia, six continuing education sessions, and two information sessions; of which nine workshops, five symposia, and five continuing education sessions were selected for the program.

Some of the key sessions were:

- The Male Reproductive Tract: Development, Toxicology, and Pathology
- AAV Vectors on the Move: Safety Assessment and Advancing Sciences in Gene Therapy 2nd Generation Products
- Modern Modeling Strategies to Address Uncertainty and Variability in Dose-Response Assessment
- Application of RISK21 Framework in regulatory based decision making: From business decisions to prioritization to risk assessment
- Express Yourself (or not...): The Nonclinical Safety of Oligonucleotide-Based Therapeutics

- EU-ToxRisk guidance for new approach methods (NAM)-supported Read-Across approaches
- Cannabidiol Science, Safety and Societal Impacts: Where do we stand?
- Applying Modern Toxicology to Dietary Supplements with Ancient Roots: Botanical Safety in the 21st Century
- Globally Harmonized Guidance for Dose-response Analysis and Derivation of Health-based Guidance Values for Chemicals in Food

RSESS SOT Mentoring Event:

Unfortunately, the mentoring session was not held due to cancellation of the SOT annual meeting.

Endowment Fund Details:

The Future of Regulatory and Safety Evaluation Endowment Fund was established in September 2018. This fund encourages research and training, scientific progress, collaboration, and the modernization of the fields of safety evaluation and/or regulatory toxicology. The fund, aligned with the Regulatory and Safety Evaluation Specialty Section, will be used primarily to provide a monetary award(s) to graduate students and/or postdocs based on scientific excellence and scientific progress toward novel, better, and fit-for-purpose, modern approaches to safety evaluation and/or regulatory toxicology. It can also be used to help provide support for Society of Toxicology programs that help foster sharing of knowledge related to scientific progress in the fields of safety evaluation and/or regulatory toxicology. Safety evaluation in the field of toxicology is undergoing a paradigm shift to a predictive, mode-of-action-focused discipline. Advancing the science of safety evaluation and regulatory toxicology is a sine qua non condition to creating a safer and healthier world. This Endowment Fund is intended to recognize and disseminate the value of new approaches that represent the future of safety evaluation and regulatory decision-making. As of May 2020, the Endowment Fund had \$30,000.

Newsletters:

RSESS published two newsletters during the past year – Fall 2019 and Winter 2020.

RSESS Webinars

“Cannabis: A Review of the Current State of Safety and Regulatory Considerations” on February 28, 2020

Cannabis use is increasing and increasingly being deregulated in the US and Canada. As the stigma around cannabis is lowered, the toxicological data and the various forms of exposure as a function of safety of cannabis deserves examination. How that safety information then informs the

regulations and legal status and the decisions around medical and/or recreational use of the substance are important aspects of how we view access and control of the substance.

- Tom Jonaitis, DABT (RegTox Solutions Inc), and a member of a task force for the STP to define adversity and its use in safety studies) presented a comprehensive review of recreational cannabis and its safety considerations.
- Garrett Graff, Esq. (Managing Attorney with the Hoban Law Group), provided an overview of the regulatory considerations of cannabis in both the US and Canada.
- The webinar was very well attended.

White Papers:

None

Contributions to SOT website:

Standard updates to officers, awards, and newsletters

Other Specialty Section 2019-2020 Activities:

None