Dear Colleagues,

I hope all of you and your families are all well.

It is so good to see the restrictions due to the pandemic lifting in so many countries around the globe and with Spring just around the corner we can all hopefully soon look forward to a new normal.

As part of this new normal, I like to encourage you to meet the RSESS community in less than a month at our SOT Annual Meeting in San Diego. Although I understand not all of our members will be able to join in person for various reasons we still hope to meet as many of you as possible at our RSESS reception on Wednesday, March 30th, 2022 in the Marriott Marquis San Diego Marina from 6:00 PM-7:30 PM. You will hear about our RSESS accomplishments in 2021 despite again exceptional circumstances, learn about our award winners, join the first Three-Minute- Thesis presentations for our newly established student award and simply have time to gather with colleagues and friends for a drink, some food and a lively exchange since a long time.

In addition to the in-person reception and to allow for all of our members to get first-hand RSESS information before the closure of this 2021/2022 turn we have arranged for a members Meet & Greet. Please watch out for a separate invite to come.

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President's Message

continued from page 1

This spring newsletter was again kindly put together from your RSESS officers and includes an update from the RSESS endowment fund, regulatory news regarding NHP shortages, a report from our program committee and the outcome of our officer election for 2022-2023, and award winners.

Lastly, our organization is as strong as its membership. Consider contributing to our endowment, look for ways throughout the year to volunteer, mentor a student member, and encourage other SOT members to join this great Specialty Section. Just contact me or any of our officers for more information.

Annette Körner, PhD, DABT, ERT
2021-2022
RSESS President

Endowment Fund

Dear colleague members of the RSESS,

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 sine qua non to creating a safer and healthier world.

In September 2018, when I was President of the RSESS, I worked with the SOT to establish the Future of Regulatory and Safety Evaluation Endowment Fund to encourage research and training, scientific progress, collaboration, and the modernization of the fields of safety evaluation and regulatory toxicology. The fund is intended to be primarily used to provide monetary awards to graduate students and/or postdocs based on scientific excellence and scientific progress toward novel, better, and fit for purpose approaches to safety evaluation and 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 regulatory toxicology.

This Endowment Fund is intended to recognize and disseminate the value of new approaches that represent the future of our discipline and I would like your help in making our Fund permanently endowed. Per SOT’s policy, the Fund need to reach $50,000 to become permanent. We are close and need approximately an additional $15,000 to meet this threshold. I would be immensely appreciative if you could consider making a contribution. You can find more information about the Fund here and can contribute using the online giving system here.

Thank you in advance for your help,

Sincerely,

Marie C. Fortin, PhD
RSESS President 2018-2019
Outstanding Contribution to Regulatory and Safety Evaluation Award

Starting in 2021, the Regulatory and Safety Evaluation Specialty Section (RSESS) would like to recognize an individual who has made significant contributions in areas of regulatory and safety evaluation.

Any RSESS member can nominate an individual (or self-nominate) for this award by December 1. The nomination should include a summary of key contributions in the regulatory and safety evaluation and include, but not limited to:

- Advancement or enhancement of safety evaluation.
- Development of regulation/guidance documents in safety assessment.
- Extensive contribution in regulatory and safety field.
- Major influence in the education/training/mentorship of young scientists in government, industry, and/or academia.
- Leadership and service to the field including involvement in the RSESS or other organizations related to the regulatory and safety assessment.

The nomination and nominee's CV should be submitted to RSESS at the following email address: HSheever@its.jnj.com

The awardee will be selected based on the nomination of candidates by the RSESS Awards Committee and RSESS Executive Council. The awardee will be contacted by the end of January. The awardee will be recognized at the RSESS Business Meeting/Mixer.

2022 Outstanding Contribution Award

Suzanne Fitzpatrick, PhD (FDA)

2022 Best Paper Award

Assessing Chemical Carcinogenicity: Hazard Identification, Classification, and Risk Assessment. Insight from a Toxicology Forum State-of-the-Science Workshop

in Critical Reviews in Toxicology

Susan P. Felter
Virunya S. Bhat
Philip A. Botham
David A. Bussard
Warren Casey
A. Wallace Hayes
Gina M. Hilton
Kelly A. Magurany
Ursula G. Sauer
Edward V. Ohanian

Deadline for nominations: Dec 1
Congratulations to the 2022 RSESS Trainee Award Winners!

Graduate Student Excellence Award
Elise Hickman
UNC-Chapel Hill

Induced Sputum Biomarkers of Respiratory Immune Homeostasis: A Comparative Analysis in 3rd vs 4th Generation E-Cigarette Users

Graduate Student Excellence Award
Eva Vitucci
UNC-Chapel Hill

A Novel In Vitro Model of the Alveolar Capillary Region: Bridging the Gap Between Inhalation Toxicology and Cardiovascular Disease

Postdoctoral Excellence Award
Emma Karey, PhD
NYU Grossman School of Medicine

Evaluating the Relative Inflammatory Risk of Passive Tobacco Product Emissions in Adults and Children

Postdoctoral Excellence Award
Alysha Simmons, PhD
UNC-Chapel Hill

Characterizing intra-human variation in common toxicity endpoints in differentiated primary bronchial epithelial cell cultures

International Society of Regulatory Toxicology and Pharmacology Excellence Awards:

Graduate Student: Eva Vitucci (UNC-Chapel Hill) for "A Novel In Vitro Model of the Alveolar Capillary Region: Bridging the Gap Between Inhalation Toxicology and Cardiovascular Disease"

Postdoc: Dinesh Babu, PhD (University of Alberta) “Edaravone (Radicava®) as an antioxidant adjuvant to attenuate clozapine (Clozaril®) toxicity in vitro”

Congratulations to the Incoming RSESS Officers for 2022

Senthil Pk
Vice President-Elect

Jessica Sapiro
Junior Councilor
Elsevier Award: Three-Minute Thesis (TMT)

Thanks to a 5-year grant from Elsevier, RSESS has created a new trainee award, the Three-Minute Thesis (TMT). This award will serve as a new platform for student members (undergraduate and graduate students) to showcase their current thesis research project within a short, 3-minute time limit. Presentations will be judged on overall scientific merit, including relevance to regulatory toxicology or safety evaluation, a graphical abstract presentation, and ability to successfully communicate the goals of their research and answer questions.

The RSESS Executive Committee will convene a diverse panel to select presenters from the pool of applicants to present in the RSESS Mixer Event. Among others, a key criterion for selection is the relevance work to regulatory safety, risk assessment or closely related aspects of research. At the RSESS mixer, students will use the graphical abstract (1 slide) to present the basis of their research (max 3 minutes) followed by 1-2 minutes for Q&A. Students will be informed of the presentation approximately 1 month ahead of the mixer.

The goal of the TMT is to provide a platform for students to practice organizing, distilling, and communicating their research to non-experts in a limited timeframe (“elevator speech”). Through this exercise, students will learn how to present their thesis research in an effective way that highlights the scientific question, main findings and their merit, the overall impact to the field.

The top 3 student presentations selected by the panel of judges will receive monetary prizes ($500 for 1st place and $250 each for 2nd and 3rd place).

Student members who wish to be considered should submit a standard meeting abstract (abstract will need to be accepted by SOT to be eligible for consideration) along with a graphical abstract (like those requested by many journals). Note: the deadline for the 2022 meeting has past, please be on the lookout for the 2023 meeting award announcement later in the year. Full details can be found on the RSESS Awards website.

Graduate Student Corner

Greetings,

There are so many wonderful events, opportunities, and workshops in store for you this year through SOT that I hope you are able to take advantage of. Congratulations to all of our Specialty Section graduate student members who are defending their dissertation this spring, we are very proud of you and wish you the greatest success in your future endeavors. With that, please take advantage of the upcoming SOT sponsored opportunities for you to network and or gain professional development nuggets regardless of where you are in your current graduate training. Please feel free to email me with any opportunities you would like to share with the larger group and we will be sure to share them. Additionally, if there are any specific things as students you would like us to cover let me know as well. I look forward to meeting many of you at the SOT Annual Meeting later this month.

Stay well and stay safe,
Carmen Amelia Marable, MPH
RSESS Graduate Student Representative

2021 - 2022 RSESS Board

President
Annette Körner, PhD, DABT, ERT
Vice President
Kristina Chadwick, PhD, DABT
Vice President-Elect
Hilary Sheevers, PhD
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Councilor
Sherleen Adamson, MD, PhD, DABT
Postdoctoral Rep.
Skye Kelty, PhD
Grad Student Rep.
Carmen Amelia Marable, MPH
Numerous session proposals for the 2022 SOT Annual Meeting were received and requested RSESS endorsement. Nine asked for primary endorsement and 6 each asked for secondary or tertiary endorsement. Of the submitted proposals, over 75% were selected into the program! Congratulations to the following courses and sessions that were endorsed by RSESS and accepted into the 2022 program:

**Continuing Education Courses**
- Animal-Free Safety Assessment of Consumer Products and Ingredients: A Primer (Sunday, March 27, 8:15 AM to 12:00 Noon, Continuing Education Course AM01)
- Importance of Sexual Maturity and Reproductive Senescence in Laboratory Animal Models (Sunday, March 27, 8:15 AM to 12:00 Noon, Continuing Education Course AM05)
- Principles and Applications of Read-Across in Human Health Risk Assessment (Sunday, March 27, 1:15 PM to 5:00 PM, Continuing Education Course PM12)

**Informational Sessions**
- Honor Thy Stakeholders: How Toxicologists Can Better Incorporate Stakeholders into Research, Communication, and Translation (Tuesday, March 29, 8:00 AM to 10:45 AM)
- How Does Your Study Measure Up? The Evolution of Study Quality Evaluations in Toxicology and Risk Assessment (Thursday, March 31, 8:30 AM to 11:15 AM)

**Roundtable Sessions**
- Tg.rasH2 Positive Controls: Added Value or No Longer Necessary? (Tuesday, March 29, 11:00 AM to 12:20 PM)
- Are Animal Studies Still the “Gold Standard” for Validating New Approach Methods? (Wednesday, March 30, 11:00 AM to 12:20 PM)

**Symposium Session**
- Optimizing the Design of Repeated-Dose Animal Studies to Inform Human Health Risk Assessment by Integrating Exposure, In Vitro, and In Silico Data (Thursday, March 31, 8:30 AM to 11:15 AM)

**Workshop Sessions**
- Leveraging Physiologically Based Pharmacokinetic (PBPK) Modeling for Refining Safety Assessment of Food, Drugs, and Chemicals under Data-Rich and Data-Poor Conditions (Monday, March 28, 9:15 AM to 12:00 Noon)
- Up to the Task? Quantitative Evaluation Criteria for Physiologically Based Pharmacokinetic (PBPK) Models (Monday, March 28, 1:45 PM to 4:30 PM)
- Building the Toolbox: Three-Dimensional Tissue Constructs as Problem Solvers (Tuesday, March 29, 8:00 AM to 10:45 AM)
- Mode of Action, Adverse Outcome Pathways, and Key Characteristics (KCs): Proposed Steps Forward and Mid-Course Corrections (Tuesday, March 29, 8:00 AM to 10:45 AM)
- Addressing the Toxicology of Newly Decriminalized Drugs (Tuesday, March 29, 1:00 PM to 2:30 PM)
- How Can We Break Down the Silos of Epidemiology, Biological Mode of Action (MOA), and Statistical Modeling in Cancer Risk Assessment? (Wednesday, March 30, 8:00 AM to 10:45 AM)
- Current Status and Future Outlook of Developmental Immunotoxicity Testing (Wednesday, March 30, 1:30 PM to 4:15 PM)
- Workshop Session: Tools for Modernizing Ecological Risk Assessment (Wednesday, March 30, 1:30 PM to 4:15 PM)

Thank you to the members of the Scientific Program Committee for once again stepping up to the plate and providing thorough scientific feedback and timely contributions: Sherleen Adamson, Dave Allen, Krisa Camargo, Cynthia Heinlein, Claire Neilan (co-chair), Logeswari Ponnusamy, and Matthew Taylor.

For those who’d like to be part of the review team, please reach out to Claire Neilan (cneilan@ideayabio.com) and get rewarded by a great experience! Not only will you be able to give back and shape SOT’s program, but you also will receive a pre-sneak on the hot topics in toxicology.
In addition to upending all of our personal and professional lives, the COVID-19 pandemic has had some perhaps less well appreciated effects. One of these has been on the supply of nonhuman primates (NHPs) available for pharmaceutical testing. In the early days of the pandemic, China imposed a trade ban on all wild animals, including NHPs, on the premise that the wild animal trade could be contributing to the spread of SARS-CoV-2. This had an immediate and drastic effect on the availability of NHPs for pharmaceutical testing, since China was the source for 60% of the NHPs imported into the US, prior to the pandemic. This ban remains in effect. While expanded domestic breeding programs and increased exports from other countries may eventually be able to fill the gap created by China’s ban, it takes time for other suppliers to be able to source sufficient animals, and for new foreign exporters to be vetted and licensed for importing NHPs into the US. At the same time that the supply was restricted, there was an increase in demand for NHPs for testing products intended to treat or prevent SARS-CoV-2 infection. FDA heard from the (bio)pharmaceutical industry, and the contract research organizations (CROs) that conduct studies with NHPs, that they are experiencing significant delays in being able to schedule studies in the NHP, especially embryofetal development (EFD) or enhanced pre- and post-natal development (ePPND) studies, since sexually mature NHPs are in particularly acute shortage.

In response, FDA drafted guidance for industry: Nonclinical Considerations for Mitigating Nonhuman Primate Supply Constraints Arising from the COVID-19 Pandemic, under our COVID-19 health emergency authority, which is intended to assist Sponsors in mitigating the effects of the NHP shortage on their development programs, by increasing reliance on other animal models and decreasing the number of animals used in some studies, wherever scientifically appropriate. Most of the elements of the guidance simply stress the flexibility already available to Sponsors under existing guidance; however, some elements represent a temporary change in guidance while the COVID-19-related disruption in the NHP supply persists. As an example of a temporary change in guidance, ICH S6(R1) indicates that there is a “preference” for conducting warranted EFD/ePPND studies with the clinical candidate in the NHP, if the NHP is the only pharmacologically relevant species, rather than using alternative models, such as a rodent-specific surrogate or a rodent model genetically engineered to be responsive to the clinical candidate; however, the NHP COVID-19 guidance recommends the use of non-NHP models for these studies whenever scientifically appropriate. The guidance also recommends that Sponsors select a nonrodent species other than the NHP for small molecule toxicology studies, unless they can provide a scientifically compelling reason why the NHP is the only relevant species. As a final example of a temporary change, the guidance indicates that for biologics acting on a well-characterized target, it may be acceptable to conduct warranted toxicology studies only in the rodent, on a case-by-case basis. “Well-characterized,” in this context, means a biologic for which there are already one or more approved products in the class, and for which there is a good understanding of safety issues based on the mechanism of action and the pathway, or based on other information (e.g., a sufficient body of generally accepted scientific knowledge) that can be used to inform the risk assessment.

This guidance, which can be found here, was co-issued by CDER, CBER and the Oncology Center for Excellence.
UPCOMING EVENTS

RSESS Membership
Virtual Meet & Greet

Tentatively scheduled for May 4
Please stay tuned for invitation after SOT

The RSESS EC would like to provide an opportunity to their RSESS members to connect after the SOT Annual Meeting and to hear an update on the 2021/2022 RSESS business, the award recipients and the overall activities of the specialty section. In addition, we like to inform about the future of the NEW RSESS endowment fund initiative and invite the membership for participation and lively exchange. Please join us by Zoom!

RSESS Webinar:
Safety of COVID-19 Therapies and Vaccines
Kenneth L. Hastings, DrPH, DABT, ATS
Tentatively scheduled for May 18
Please stay tuned for invitation after SOT

Since the pandemic outbreak of COVID-9 beginning in 2019, several vaccines have been developed to help prevent the onslaught of acute disease. In the US, three products were granted emergency use approval (EUA), including two mRNA-generated vaccinations, and one traditional vaccine generated by viral vector. The mRNA vaccinations (Pfizer-Biotech and Moderna) have been fully approved in the US. In the meantime several therapeutics have been given EUA in the US, including Pfizer’s Paxlovid and Merck’s Molnupiravir, and monoclonal antibody treatment. The single approved drug for COVID-19 in the US is remdesivir, originally approved for Ebola, but found to have some activity against COVID-19. The webinar will focus on safety and efficacy of the approved and EUA vaccines and therapeutics for COVID-19, as well as upcoming approaches for vaccinations and therapeutics in light of the variants being found globally.

SOT
Events
Calendar

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Student/Postdoctoral Scholar Mixer

Sunday, March 27, 7:30 PM to 9:00 PM at SOT
The Student/Postdoctoral Scholar Mixer is an opportunity to build valuable relationships with colleagues and learn more about others’ experiences as a graduate student or postdoc.

Please consider a donation to the RSESS Endowment Fund

Contributions to the RSESS Endowment Fund 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.

To donate – please visit the RSESS website: SOT RSESS | Endowment Fund (toxicology.org)

You can access the online giving system or download the Donation Form to make a gift to the Future of Regulatory and Safety Evaluation Endowment Fund.