



Fall 2026 Newsletter



President's Message

Dear RSESS Members,

It is a tremendous honor and privilege to serve as President of the Regulatory and Safety Evaluation Specialty Section (RSESS) for 2026–2027. I would like to sincerely thank our past leaders, volunteers, committee members, and all of you whose dedication and engagement have made RSESS one of the most active and impactful Specialty Sections within the Society of Toxicology.

Regulatory science continues to evolve rapidly as advances in New Approach Methodologies (NAMs), artificial intelligence (AI), global harmonization initiatives, and changing regulatory expectations reshape the practice of toxicology. More than ever, RSESS serves as a forum that brings together scientists from industry, academia, regulatory agencies, and consulting organizations to exchange ideas, discuss emerging challenges, and advance regulatory science through webinars, scientific programming, professional development activities, and collaborative initiatives.

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President's Message (cont.)

One of my priorities this year is to broaden opportunities for engagement across all career stages. While RSESS has a strong tradition of recognizing outstanding students and early- and late-career scientists, many members reach a pivotal mid-career stage where they make significant contributions to regulatory science while also taking on leadership responsibilities, mentoring future scientists, and building cross-sector collaborations. I am excited to introduce a new award recognizing outstanding contributions by mid-career regulatory and safety scientists. By celebrating excellence throughout the professional journey, we can better acknowledge the diverse accomplishments that strengthen our profession. I encourage all members to visit the RSESS webpage to learn more about our awards program and consider submitting applications.

Another key objective is to expand collaboration with other SOT Specialty Sections. Many of today's scientific and regulatory challenges extend beyond traditional disciplinary boundaries, making interdisciplinary engagement more important than ever. By partnering on webinars and scientific programs focused on topics of shared interest, we can bring together broader expertise, encourage productive dialogue, and provide greater value to our members. These collaborations also create valuable networking opportunities and strengthen connections across the SOT community. I am pleased to share that we already have two collaborative webinars planned for later this year, and I encourage you to watch for upcoming announcements and registration details.

The SOT Annual Meeting remains our flagship scientific event, and RSESS has consistently contributed to the high-quality scientific program. This year, we received a record number of scientific program proposals for review, and RSESS members

actively participated in providing pre-review feedback and recommendations. These efforts help shape the scientific content of the 2027 SOT Annual Meeting and ensure that emerging topics relevant to regulatory and safety sciences are well represented.

Finally, I encourage each of you to become actively involved in RSESS — whether by serving on a subcommittee, participating in webinars as a speaker or a co-moderator, mentoring colleagues, nominating deserving award candidates, or sharing suggestions with the Executive Committee. Our Specialty Section thrives because of the enthusiasm, expertise, and commitment of its members. If you are interested in becoming more involved, please reach out to any member of the Executive Committee or one of our subcommittee leaders. I also encourage you to follow the [SOT Regulatory and Safety Evaluation Specialty Section on LinkedIn](#) to stay informed about upcoming events, opportunities, and announcements.

Thank you for your continued support and engagement. Together, we can build on RSESS's strong foundation while creating new opportunities for collaboration, recognition, scientific excellence, and professional development.

I look forward to working with all of you and to an exciting and productive year ahead.

Warm regards,

Manoj Aggarwal, DVM, PhD, DABT
President, 2026–2027
Regulatory and Safety Evaluation
Specialty Section (RSESS)
Society of Toxicology (SOT)



**REGULATORY &
SAFETY EVALUATION**
Specialty Section

LEADERSHIP

2026-2027 RSESS Leadership:

Elected Officers		
Role	Name	Email
President	Manoj Aggarwal	manoj.aggarwal@merck.com
Vice President	April O'Connell	AprilDML2002@gmail.com
Vice President-Elect	William D. Klaren	wklaren@toxstrategies.com
Past President	Claire Neilan	cneilan@ideayabio.com
Secretary/Treasurer	Dahea You	dhyou21@gmail.com
Senior Councilor	Timothy McGovern	timmcgovern7@gmail.com
Junior Councilor	Madelyn Huang	madelyn.huang@premierconsulting.com
Postdoctoral Representative	Aishwarya Rengarajan	aishwarya.rengarajan@merck.com
Graduate Student Representative	Hannah Roe	hannah.roe.1@tamu.edu
Appointed Officers		
Role	Name	Email
Program Committee Chair	Nikolaos Georgiadis	nikolaos.georgiadis@ec.europa.eu
Endowment Committee Chair	Madelyn Huang	madelyn.huang@premierconsulting.com
Guidance Committee Co-Chairs	Stephene Ford	sford@viridiantherapeutics.com
	Erik K. Pacyniak	Erik.Pacyniak@alcon.com

Introduction of New Committee Leaders

RSESS is excited to welcome and introduce the new RSESS committee leaders!



Stephene Ford – Guidance Subcommittee Co-Chair

Stephene H. Ford, BS, MBM is the Director of Toxicology at Viridian Therapeutics. She provides strategic leadership for nonclinical safety assessment programs supporting drug development from discovery through late-stage clinical development.



Erik K. Pacyniak – Guidance Subcommittee Co-Chair

Erik K. Pacyniak, PhD, DABT is the Director of Pharmacology, Toxicology and Drug Disposition at Alcon, where he provides strategic leadership for nonclinical safety assessment programs supporting drug development from discovery through late-stage clinical development. He has led nonclinical strategies supporting multiple INDs and NDA approvals and has extensive experience in global regulatory interactions, nonclinical risk assessment, and regulatory toxicology

June 2026 SOT Annual Meeting Award Winners Webinar



*Several of our RSESS award winners from the March Annual Society of Toxicology Meeting in San Diego, CA were invited to present their work on June 26th at the virtual **“Regulatory and Safety Evaluation Specialty Section 2026 Award Winners Webinar”**.*

An engaging overview of the award-winning science from the following presenters with Q&A was hosted by Manoj Aggarwal and April O’Connell.

The RSESS membership sends a special thank you for the strong presentations to each panelist! Thank you to all attendees who joined us for the 2026 RSESS Award Winners Webinar where our panelists showcased their research!

Congratulations to the 2026 RSESS Awardees!

Graduate Student Excellence Award

Rachel Kim, University of California, Los Angeles

Neurotoxicity Risk Modeling of Oral-Mucosal BPA Exposure from Dental Resin Composites: Implications for Reassessing the US EPA Standard

Hangyu Wu, University of Connecticut

Multidrug Resistance-Associated Protein 4 (MRP4) Deficiency Disrupts Hepatic Lipid Homeostasis and Exacerbates Metabolic Dysfunction-Associated Steatotic Liver Disease

Conklin-Sheevers Endowed Award (University of Arizona)

Diksha Manhas, PhD, University of Arizona

PCB-11 Induces Brain CYP2B10 Expression and Activity in Mice: Implications for Neurotoxicity and Drug Interaction Potential

Three Minute Thesis

Manisha Thakur, Southern University and A&M College

Multiwalled Carbon Nanotubes Modulate Lipid Rafts Assembly and Hippo Signaling

Postdoc Excellence Award

Zakiyah Henry, PhD, National Institute of Environmental Health Sciences

Roots to Neurons: Evaluating Developmental Neurotoxicity (DNT) Potential of Botanicals Using an In Vitro Testing Battery

Chander Kant Negi, PhD, Texas A&M University

Analysis of Species-Specific Hepatocyte Function and Drug Effects in Static Monolayers, Spheroids, and a Perfused Microphysiological System

Nicole McNabb-Kelada, PhD, RTI International

Integrating Inter-Individual Variability and Cellular Interactions: Transcriptomic Responses to Acrolein in a Donor-Matched Lung Co-Culture Model

Best Paper of the Year Award

Srijit Seal, PhD, MPhil, Merck

Machine Learning for Toxicity Prediction Using Chemical Structures: Pillars for Success in the Real World

Outstanding Contribution to Regulatory and Safety Evaluation Award

Bette Meek, PhD, University of Ottawa

Get to know some of them here:

	 Bette Meek (Outstanding Contribution to RSESS Award)	 Zakiyah Henry (Postdoc Excellence Award)	 Rachel Kim (Graduate Student Excellence Award)	 Hannah Roe (Graduate Student Excellence Award)
What is your favorite chemical?	<i>MMT- a great chemical name.</i>	<i>Garcinia Cambodia</i>	<i>Either BPA or vitamin C</i>	<i>Fluorescent brightener chemicals</i>
What has been an interesting session/ poster at this year's SOT meeting?	<i>I enjoyed the awards ceremony, getting to see people recognized for their work and reconnecting with old colleagues.</i>	<i>It was my first time chairing a session this year, which was a fantastic experience.</i>	<i>I enjoyed meeting experts and collaborators that I had been working with, in person!</i>	<i>I found a lot of value from the networking and trainee events.</i>
What do you like to do in your free time?	<i>All kinds of winter sports! Also, a big swimmer and biker.</i>	<i>I enjoy going to concerts, mostly R&B.</i>	<i>Does sleeping count?</i>	<i>Crocheting!</i>

Brought to you by the RSESS Endowment Committee.

Your donation to the RSESS endowment fund makes trainee awards like the postdoc and graduate student excellence awards possible! Scan the QR code to donate on the RSESS GiveSmart page!



Endowment Fund Subcommittee Update

The Future of Regulatory and Safety Evaluation Fund, established in 2018, supports research, training, scientific advancement, collaboration, and the continued modernization of the fields of safety evaluation and regulatory toxicology. The fund is used primarily to provide 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. As of the first quarter of 2026, the endowment fund balance was \$70,373.91. The 2026 distributable amount totaled \$2,768, all of which was used to fund graduate student and postdoctoral trainee awards presented at the 2026 Society of Toxicology Annual Meeting.

Apply for the 2027 Awards!

Do not forget to apply for currently available SOT awards!! These awards cover a range of career and education levels and are open to many. Please visit the SOT website for more details, <https://sot.toxicology.org/award>.

RSESS sponsors various awards and the application deadline is December 3, 2026. More information about each award can be found [here](#) on the RSESS webpage.

Regulatory Guidance Subcommittee Update

Stephene Ford, BS, MBM & Erik K. Pacyniak, PhD, DABT, Co-Chairs

The regulatory guidance subcommittee was formed in the fall of 2022 to alert RSESS membership of new and updated guidance as well as impactful articles in the field of regulatory and safety evaluation. The subcommittee publishes updates 2-3 times each year with the support of volunteer authors from various sectors. The RSESS would like to thank the subcommittee members for their contributions and support. If you are interested in joining the subcommittee, please contact us (sford@viridiantherapeutics.com, Erik.Pacyniak@alcon.com).

2026-2027 Guidance Subcommittee Members

Stephene Ford	James Kim	Brett Winters
Erik Pacyniak	Miao Li	Supriya Kadari
Dahea You	Naveen Kumar	Jalissa Nguyen (Winder)
Pramila Singh	Min-Sik Kim	Alyssa Cobbs
Logeswari Ponnusamy	Krista Enos	Rene Caballero-Floran
Jossie Garthoff	Azik Musa Kanadi	Sarah Owen
Gina Hilton	Lily Zhou	

Folders have been created on ToXchange in which new and recently updated guidance and articles of interest are stored. [RSESS Guidances and Articles \(Remember to log in on the SOT site to get full access.\)](#)

Please find below our latest updates.

EFSA's Scientific Opinion on Waiving of the Dog Studies in the Regulatory Process of Agrochemicals Approval

The European Food Safety Authority (EFSA) Panel on Plant Protection Products and their Residues (PPR) published a Scientific Opinion addressing when 90-day oral toxicity studies in dogs may be waived for pesticide active substances. The opinion is supported by a retrospective review of EU pesticide assessments which found that dog-specific sensitivity did not determine acceptable daily intake (ADI) values in 97% of cases. EFSA therefore proposed scientific criteria and a tiered assessment strategy to support waivers, aligning broader efforts to reduce when a dog study is unlikely to add meaningful information while maintaining robust human health risk assessment. The approach supports regulatory confidence while advancing efforts to reduce animal testing and modernize assessments.

By Gina Hilton, PhD

Oncology Pharmaceuticals: Streamlined Nonclinical Safety Studies for Biologics and Conjugated Products

The US Food and Drug Administration (US FDA) Center for Drug Evaluation and Research's (CDER's) draft guidance describes when Sponsors may be able to streamline, reduce, or replace certain animal studies for oncology biologics and conjugated products. The guidance does not recommend eliminating animal studies broadly; instead, it supports a case-by-case approach based on the product's mechanism of action, modality, available pharmacology and toxicology information, and the remaining safety questions relevant to clinical development. When the existing evidence is sufficient, Sponsors may use alternatives, including new approach methodologies (NAMs), as part of a weight-of-evidence assessment to avoid animal studies that are unlikely to add meaningful information. US FDA encourages Sponsors to discuss these proposals with CDER through formal meetings, including those described in the US FDA guidance, *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products*, so that the nonclinical safety package is appropriately tailored before key development decisions are made.

By Gina Hilton, PhD

Codex Adoption of Revised Allergen Labelling Guidance: A Science-Based Approach

Unintended allergen presence can occur during shared food storage, transport, or handling, even when that allergen is not an ingredient. Precautionary allergen labeling (PAL), such as "may contain," is intended to alert allergic consumers to this risk.

However, because PAL practices vary widely and remain unregulated in many jurisdictions, these statements can provide inconsistent information about actual allergen risk.

The revised Codex guidelines, adopted in July as an annex to the *General Standard for the Labelling of Pre-packaged Foods (CXs 1-1985)*, provides a harmonized, science- and risk-based framework for PAL. It recommends using PAL only when allergen risk cannot be adequately controlled through good allergen management practices and has been evaluated qualitatively and, when needed, quantitatively using Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) reference-dose principles. This approach provides a clearer scientific basis for determining when precautionary statements are justified.

Although voluntary, Codex guidance offers an internationally recognized benchmark for making PAL statements more consistent, meaningful, and risk-based. It may also support national regulation and trade by providing a common scientific reference for allergen risk communication.

By Jossie A. Garthoff, ERT

US FDA Proposed Rule Would Require Mandatory GRAS Notifications

On August 11, the US FDA proposed replacing voluntary GRAS notifications with mandatory submissions for substances added to human food, animal food, and food-contact materials that rely on the GRAS exemption. The rule would also expand the Threshold of Regulation pathway to certain direct food additives. Comments are due December 9, 2026.

Although the US FDA says mandatory notification would not constitute premarket approval, and firms could continue marketing GRAS substances before and after submission, the proposed technical review would increase oversight. Submissions would also give the US FDA a more complete inventory of GRAS substances and make most notifications publicly available.

For one year after the rule's effective date, the US FDA would accept streamlined submissions for GRAS substances already in interstate commerce, but could later request exposure and safety data. Companies relying on self-GRAS conclusions should ensure their data are adequate and publicly supportable; food-contact substances may still be better handled through the Food Contact Notification program when proprietary protection is important.

By Sarah Owen, PhD, DABT

Program Subcommittee Update

This year, the RSESS was honored to receive 31 proposal pre-review requests and 48 proposals for review and endorsement. Of those endorsed by the RSESS, 30 proposals were finally accepted. We are looking forward to seeing these proposals being presented at the upcoming 2027 SOT Annual Meeting in San Antonio, TX!

The RSESS would like to sincerely thank the following people for volunteering their time to thoroughly review the proposals.

Nikolaos Georgiadis

Leah Zorilla

Manoj Aggarwal

Nicholas Drury

Vijay Kannappan

William D. Klaren

Claire Neilan

April O'Connell

Matthew Taylor

Dahea You

Jennifer Yukun Zhang

Introducing Our New Career Development Corner!

This year, RSESS began a career development series highlighting various aspects of working as a toxicologist in regulatory and safety evaluation. These posts aim to share practical insights to help toxicologists navigate and advance their careers. Featured topics to date included evaluating whether a consulting company is the right fit, exploring the diverse roles toxicologists play throughout drug development, building and maintaining a strong professional network, and refreshing your resume to highlight new experiences and accomplishments. Whether you're just starting your career or considering your next move, we hope these posts offer practical advice and actionable tips to support your professional growth.

Follow [RSESS on LinkedIn](#) to stay up to date with future career development content and discussions. Also, all previous posts can be viewed on Toxchange. If you have ideas for topics you want to hear about, let us know! Message us on LinkedIn or email rsessot@gmail.com.

Graduate Student and Postdoc Update:

Hello, fellow RSESS trainees!

We are looking forward to serving and getting to know you as the next year unfolds. Congratulations to all the trainees who won awards at the 2026 SOT meeting and gave great presentations at our webinar in June! That said, it is already time to start learning about all the RSESS awards for SOT 2027; applications are due on December 3rd. We also plan to share resources with you through these newsletters and on the RSESS LinkedIn page throughout the year. In fact, there are some updated resources available in this newsletter for you to check out!

We would love to hear from you. Please share ideas for future trainee programming, questions about RSESS involvement, or announcements you would like featured in a future update. We look forward to supporting your scientific, professional, and networking goals throughout the year.

Best,

Hannah Roe
RSESS Graduate Student Representative

Aishu Rengarajan, PhD
RSESS Postdoctoral Representative

Professional Development Resources for Trainees

Toxicology basics

- Key principles of toxicology - [Welcome to ToxTutor - Toxicology MSDT](#)
- Toxicology education foundation - [Home - Toxicology Education Foundation](#)
- Alternative Methods - [NICEATM: Alternative Methods](#)
- Continuous education course recordings - [Free access to CE Course recordings](#)

External presentations and manuscripts

- Publishing advice and guidance - [Publishing advice and guidance | Oxford Academic](#)
- Poster presentations - [The Importance of Poster Presentations at Scientific Meetings: How to Make the Most of It](#)

Careers/jobs

- Guide to industry toxicology jobs - [Want an Industry Toxicology Job? Start by Understanding the “Toxicologist Ecosystem”](#)
- Careers in regulatory toxicology - [Careers in Regulatory Toxicology—Society of Toxicology](#)
- Becoming a toxicologist - [Becoming a Toxicologist—Society of Toxicology](#)
- Job bank - [SOT Job Bank](#)

Resume writing tips

- [How to Write Effective Resumes and CVs for Doctoral Students and Postdocs – Imagine | Johns Hopkins University](#)
- [PhD/Postdoc Sample Resumes – Career Services | University of Pennsylvania](#)

Internships

- Internship resources - [Internship Resources—Society of Toxicology](#)

Mentorship

- Mentor match - [SOT Mentor Match](#)

Upcoming Events

The RSESS is co-hosting the following webinars with the SOT Sustainable Chemicals through Contemporary Toxicology Specialty Section (SCCT), the SOT Biotechnology Specialty Section, and the SOT Drug Discovery Specialty Section. Join us to learn about contemporaneous topics in the field of Toxicology and to engage in scientific discussion with peers.

Third party certifications- what they mean, what/who they're for, and how they impact safer chemical selection

Date/Time: Fall 2026

Registration is required for this free webinar

Tentative Speakers

Tim Sherry, OEKO-Tex – Certification for Textiles

Holly Elwood, EPEAT – Certification for Electronics

TBD – Certification for Cleaning Products and Safer Choice Options

TBD – Certification for Personal Care products

More details to follow!

Transforming Toxicology Data into Enduring Knowledge: Outcomes and Benefits of SEND Data Submission

Date/Time: Thu, Dec 3, 2026 from 01:00 PM to 02:00 PM (ET)

[Registration is required for this free webinar](#)

Speakers

- Stephanie Leuenroth-Quinn, PhD, Associate Director for Pharmacology and Toxicology, CDER/OND/IO US Food and Drug Administration
- Kevin Snyder, PhD, Director of Nonclinical Innovation and Emerging Technologies, Certara

SEND data submission is often viewed as a regulatory obligation, yet its value extends well beyond compliance. In the near term, SEND delivers acute outcomes through improved data quality, greater study transparency, and more efficient regulatory review. Over time, standardized datasets become durable scientific assets that support cross-study analyses, translational research, and emerging computational approaches. This presentation highlights how SEND enables the transformation of toxicology data into reusable knowledge that continues to generate value long after a study is completed. Attendees will gain perspective on the chronic benefits of SEND for data stewardship, scientific innovation, and maximizing insights from nonclinical studies.

ICH S13 Draft Guideline: The Well-Characterized ONT and Opportunities for Nonclinical Development

Date/Time: Thu, Jan 14, 2027 from 11:00 AM to 12:00 PM (ET)

[Registration is required for this free webinar](#)

Speakers

- Tod Harper, PhD, DABT, Scientific Director, Amgen
- Xuan Chi, PhD, Supervisory Pharmacologist, US FDA
- Jen Sisler, PhD, DABT, Director of Toxicology, Eli Lilly

The draft ICH S13 guidance, Nonclinical Safety Evaluation of Oligonucleotide-Based Therapeutics, introduces a harmonized framework for the nonclinical development of oligonucleotides (ONTs). This webinar will provide a high-level overview of the guidance, with emphasis on the well-characterized ONT concept and opportunities to leverage prior knowledge to support more focused, efficient, and scientifically justified nonclinical programs. Additional discussion will highlight risk-based, WoE approaches, new approach methodologies, and other ONT-specific considerations that may enable more tailored development strategies. A panel of ICH S13 Expert Working Group members will discuss the draft guidance and address questions during a panel discussion and Q&A.

Fall 2026 Newsletter Editors

Dahea You

Manoj Aggarwal

April O'Connell

William D. Klaren

Madelyn Huang

Stephene Ford

Erik K. Pacyniak

Aishwarya Rengarajan

Hannah Roe