President’s Message

Dear BTSS Members,

We look forward to seeing you at the SOT Annual Meeting!

Please stop by the BTSS Reception on Wednesday at 6:00-7:30 pm to congratulate our award recipients, welcome the incoming Executive Committee, and enjoy food and libations generously provided by Genentech.

For Annual Meeting events to look forward to, BTSS is sponsoring a graduate student mentoring lunch on Tuesday, and endorsing an exciting line-up of CE Courses and Sessions – please attend!

Help me welcome the newly elected officers and incoming BTSS Executive Committee for 2018-2019 - see page 5 for election results.

A big thank you to Tom Gelzleichter (Past-President), Jacintha Shenton (outgoing Councilor) and Amy Sharma (Secretary/Treasurer) for their years of service to the Committee and BTSS!

Finally, thank you to our members for your continued support and participation. Please reach out to the Executive Committee with any ideas you may have for 2018-2019.

See you in San Antonio!

Best,
Janice

Student/Postdoc Corner

Greetings BTSS Students and Postdocs!

Myself and Kshama Doshi (our postdoc rep) would like to welcome you all to another SOT Annual Meeting! While it’s tough to prioritize during all of the exciting events to SOT, we hope you will come out to our Mentoring Lunch. New this year, we are hosting a lunch meeting (with sangria!) to give you a chance to network with industry experts in a casual setting. See page 5 for details!

Next, having met cool BTSS people, we hope you can make it to the kids table at the BTSS Reception on Wednesday. This is no ordinary specialty section reception - Genentech has sponsored complementary drinks this year! Free food and libations = graduate student heaven! We are excited to see old science friends and meet new people who want to get involved in BTSS!

See you next week! - Joe

Interested in contributing to future BTSS newsletters? We would love your input! Contact Joe Jilek—jljilek@ucdavis.edu
President
Janice Lansita, PhD, DABT
ToxStrategies

Vice President
Jorg Blumel
PhD, ERT
Genentech

Vice President-Elect
Kelly Flagella, PhD, DABT
Ultragenyx

Past President
Thomas Gelzeichter, PhD, DABT
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Secretary/Treasurer
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Senior Councilor
Jacintha Shenton, PhD
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Student Rep
Newsletter Editor
Joseph Jilek, MS
UC Davis

Junior Councilor
Robert Li, PhD, DABT
Genentech

Postdoc Rep
Newsletter Editor
Kshama Doshi, PhD, MS
Boston University

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2018 Award Recipients

- **Career Achievement**
  Helen Haggerty, Ph.D. - Bristol-Myers Squibb

- **Young Investigator**
  Robert Li, Ph.D., DABT - Genentech

- **Battelle Postdoctoral Award**
  Xi Li, Ph.D. - Texas A&M

- **Student Achievement**
  Nehal Gupta - Texas Tech
  Muthanna Sultan - University of South Carolina

- **Best Paper**
  Christina Zuch de Zafra et. al.
  Inflammation and immunogenicity limit the utility of the rabbit as a nonclinical species for ocular biologic therapeutics.
  *Regulatory Toxicology and Pharmacology* 86:221-230
2018 Annual Meeting Reception

Wednesday, March 14th
6:00—7:30 P.M.
Grand Hyatt Texas B

Come catch up and enjoy the company of fellow BTSS members! We will be recognizing annual award winners and hearing from the 2018 Career Achievement awardee.

BUT WAIT, there’s MORE!

As a thank you for staying through the entire Annual Meeting, our colleagues at Genentech are providing the drinks! Don’t miss out on the free drinks (and give Jorg a shout out for securing this!)

Genentech

BTSS FINANCIALS
Net Assets at the end of November 2017: $ 12,404
Attention students and postdocs - don’t miss the BTSS Mentoring Lunch at SOT 2018!

Come enjoy lunch and libations on BTSS, meet some awesome industry experts, and get your career questions answered!

Mentors Include:
- Joe Francisco - Charles River
- Amy Sharma - Genentech
- Matthew Holdren - Genentech
- Jeanine Bussiere - Amgen

Details:
- Tuesday, March 13th from 11:30 A.M.—1:00 P.M.
- Rosario’s Southtown (910 S. Alamo St., San Antonio, TX 78205)
- RSVP to Joe Jilek at jljilek@ucdavis.edu

Election Results

You voted, here they are! Your 2018-2019 BTSS Executive Committee:
- Vice President-Elect: Amy Sharma
- Junior Councilor: Ken Oliver
- Postdoc Representative: Kshama Doshi
- Graduate Student Representative: Joe Jilek

They will be joining Jorg Blumel (President), Kelly Flagella (Vice-President), Janice Lansita (Past-President), and Robert Li (Senior Councilor) to round off the team.

Please note: Amy’s election to the presidential chain leaves the Treasurer/Secretary position open. We will be holding a special election in the near future!
Biotherapeutic Development: What’s Behind the Curtain?

Sunday, March 11 - 8:15 A.M. to Noon

Chairs: Laura Andrews (AbbVie) and Mary Ellen Cosenza (MEC Regulatory & Toxicology Consulting)

♦ Jorg Blumel (Genentech) - It’s Not Smoke and Mirrors: Demystifying Nonclinical Development Strategies for Biotherapeutics
♦ Maggie Dempster (GlaxoSmithKline) - Relevant Species Selection: Is It as Easy as Pulling a Rabbit Out of a Hat?
♦ Robert Caldwell (AbbVie) - Managing Immunogenicity: Now You See It and Now You Don’t
♦ Christopher Ellis (US FDA) - The Final Curtain: Regulatory Insights on the Development of Biotherapeutics; Where Are We Now?

NGS-Based Technologies Enable Biomarker Development and Discovery in Toxicology

Sunday, March 11 - 1:15 to 5:00 P.M.

Chairs: Alex Merrick (NIEHS) and Andrew Nixon (Duke University)

♦ Bruce Merrick (NIEHS) - Next-Generation Sequencing Platforms in Toxicology
♦ Andrew Nixon (Duke University Medical Center) - Biomarker Development and Application to Toxicology
♦ Julia Yue Cui (University of Washington) - Long Noncoding RNAs: A Novel Paradigm in Toxicology
♦ Brian Chorley (US EPA) - Next Generation Sequencing Applications for MicroRNA Biomarker Discovery in Toxicological Studies
♦ Julie Foley (NIEHS) - Whole Exome Sequencing in Toxicology
♦ David Volz (University of California, Riverside) - Leveraging Illumina-Based Sequencing to Reveal Chemically-Induced Alterations in Genome-Wide Cytosine Methylation

*** Please note: CE courses require a ticket. See SOT website for details***
BTSS-Sponsored Events

Scientific Session

Understanding the Molecular Mechanisms of Zika Virus Reproductive and Developmental Toxicity
Monday, March 12 - 9:15 A.M. to Noon - Stars at Night Ballroom B2
Chairs: Pedro Del Valle (US FDA) and Elena Hernandez-Ramon (NIH)

- Ricardo Rajsbaum (University of Texas Medical Branch) - The role of the Host Ubiquitin System in Zika Virus Replication and Tissue Tropism
- Jean Pierre Peron (University of São Paulo) - Zika Congenital Syndrome in Murine Experimental Model
- Prabagran Esakky (Washington University School of Medicine in St. Louis) - Mouse Model of Zika Virus Infection in Testis and its Potential Relevance to Mechanism of Infection in Human Testis and Male Infertility
- Rafael Larocca (Harvard Medical School) - Protective Efficacy of Multiple Vaccine Platforms against Zika Virus Challenge in Rhesus Monkeys
- Elizabeth Mendez (US EPA) - Integrated Pest Management: A Multifaceted Approach to Vector Control

Workshop

Nonclinical to Clinical Translation of Antibody-Drug Conjugates
Thursday, March 15 - 8:30 to 11:15 A.M. - Room 301
Chairs: Subbu Karanth (Medimmune) and Amy Sharma (Genentech)

- Nicola Stagg (Genentech) - Translational Value of Nonclinical Safety Studies
- Haley Neff-LaFord (Seattle Genetics) - Safety Perspectives Including Class Effects and Off-Target Toxicity
- Whitney Helms (US FDA) - A Regulatory Update on Nonclinical Expectations to Support the Safety of ADCs
- Mary Jane Hinrichs (Medimmune) - Translational Strategies to Maximize Therapeutic Index of ADCs