

# STP 35<sup>TH</sup> ANNUAL SYMPOSIUM

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THE BASIS AND RELEVANCE OF  
VARIATION IN TOXICOLOGIC RESPONSES

## PROGRAM



SAN DIEGO • CALIFORNIA  
JUNE 26–30, 2016

# ANNUAL SYMPOSIUM OVERVIEW

All events are in the Manchester Grand Hyatt San Diego hotel unless otherwise indicated. Halls are 1st floor and Cortez is 3rd Floor.

## 24 FRIDAY

4:00 PM–6:00 PM Registration Grand Hall Foyer

## 25 SATURDAY

8:00 AM–6:00 PM Registration Grand Hall Foyer

9:00 AM–4:30 PM NTP Satellite Symposium Grand Hall A

7:00 PM–10:00 PM Sponsored Reception (*Charles River and WIL Research*) Marina Courtyard

## 26 SUNDAY

7:00 AM–6:00 PM Registration Grand Hall Foyer

8:00 AM–12:00 Noon Career Development Workshop: Toxicity Testing in the 21st Century: Will *In Vivo* Studies Become Obsolete? Cortez Hill B

 8:00 AM–12:00 Noon Morning Continuing Education Courses

CE1: The Respiratory System As a Target for Drug-Induced Toxicity: Pathology and Investigational Techniques Grand Hall A

CE2: Interpreting and Integrating Clinical and Anatomic Pathology Results: Pulling It All Together Grand Hall B

 1:30 PM–5:30 PM Afternoon Continuing Education Courses

CE3: Hematotoxicity and Immunotoxicity Assessment: Essential Principles and Emerging Modalities Grand Hall A

CE4: Is It Adverse, Adaptive, Artifact? Grand Hall B

5:30 PM–7:00 PM STP Welcome Reception/Exhibits Opening Grand Hall C

7:00 PM–8:30 PM Student/Mentor Mixer (*Registration Required*) (*Sponsored by EPL, Inc. and Envigo*) Torrey Hills A

## 27 MONDAY

7:00 AM–5:30 PM Registration Grand Hall Foyer

8:00 AM–9:00 AM Symposium Welcome and Keynote Address: Cornerstones of Toxicology Grand Hall A

9:00 AM–12:00 Noon Session 1 (AM): Real World Toxicology Outcomes: Impact of Species and Strain Selection on Drug Development Programs Grand Hall A

9:00 AM–4:00 PM Exhibits and Poster Sessions Open Grand Hall C

9:55 AM–10:25 AM Break (*Sponsored by Covance Laboratories, Inc.*) Please visit the Exhibits and Poster Sessions. Grand Hall C

12:00 Noon–1:30 PM Exhibitor-Sponsored Lunch for Registered Symposium Attendees Grand Hall C

12:30 PM–1:30 PM Career Development Lunchtime Series: Interacting with Our MD Colleagues Cortez Hill B

1:30 PM–5:00 PM Session 2 (PM): Deciphering Sources of Variability in Clinical Pathology—It's Not Just About the Numbers Grand Hall A

3:20 PM–3:50 PM Break (*Sponsored in part by Syngenta*) Please visit the Exhibits and Poster Sessions. Grand Hall C

## 28 TUESDAY

7:00 AM–12:00 Noon Registration Grand Hall Foyer

8:00 AM–12:00 Noon Session 3 (AM): Influence of Experimental Design and Environmental Conditions Grand Hall A

9:00 AM–12:00 Noon Exhibits and Poster Sessions Open Grand Hall C

9:20 AM–10:00 AM Break (*Sponsored in part by Eli Lilly and Company*) Please visit the Exhibits and Poster Sessions. Grand Hall C

12:15 PM–1:15 PM Exhibitor-Hosted Session Cortez Hill B

12:15 PM–4:00 PM Student Outing (*Sponsored by EPL, Inc. and Envigo*) Hillcrest A

Tuesday Afternoon FREE TIME

## 29 WEDNESDAY

7:30 AM–5:30 PM Registration Grand Hall Foyer

8:00 AM–12:00 Noon Session 4A (AM): Influence of Epigenetics, Genetics, and Immunology (Part 1) Grand Hall A

9:00 AM–11:30 AM Exhibits and Poster Sessions Open Grand Hall C

10:05 AM–10:40 AM Break Please visit the Exhibits and Poster Sessions. Grand Hall C

12:00 Noon–1:30 PM Postnatal Organ Development As a Complicating Factor in Juvenile Toxicity Studies—*Sponsored by IATP and STP* Cortez Hill B

1:30 PM–5:00 PM Session 4B (PM): Influence of Epigenetics, Genetics, and Immunology (Part 2) Grand Hall A

2:55 PM–3:25 PM Break Grand Hall Foyer

5:30 PM–5:50 PM Awards Ceremony Grand Hall A

5:50 PM–6:30 PM Annual Business Meeting Grand Hall A

7:00 PM–9:00 PM President's Reception Grand Hall C

## 30 THURSDAY

7:30 AM–12:00 Noon Registration Grand Hall Foyer

8:00 AM–12:00 Noon Session 5 (AM): Influence of Age, Hormones, and the Microbiome Grand Hall A

10:05 AM–10:40 AM Break Grand Hall Foyer

12:00 Noon Meeting Adjourned

# Welcome!

From the STP President

Dear Colleagues and Guests,

On behalf of the Society of Toxicologic Pathology, welcome to the STP 35th Annual Symposium at the Manchester Grand Hyatt in San Diego, California. The 2016 Scientific Program Planning Committee has planned an outstanding week of sessions on "The Basis and Relevance of Variation in Toxicologic Responses." I encourage you to take a few minutes to review the schedule of scientific and poster sessions and special events in this Program to get the most benefit from the week ahead.

The interactive NTP Satellite Symposium, "Pathology Potpourri," will be held all day Saturday, June 25, and will focus on presentations of challenging lesions. It is free to all attendees.

You may still register for one or more of the Continuing Education sessions by stopping by the STP Registration Desk just outside the Exhibit Hall. Four optional half-day Continuing Education (CE) courses include: The Respiratory System As a Target for Drug-Induced Toxicity: Pathology and Investigational Techniques (CE AM1), Interpreting and Integrating Clinical and Anatomic Pathology Results: Pulling It All Together (CE AM2), Hematotoxicity and Immunotoxicity Assessment: Essential Principles and Emerging Modalities (CE PM3), and Is It Adverse, Adaptive, Artifact? (CE PM4).

There will be two Career Development programs offered this year. The Career Development Workshop "Toxicity Testing in the 21st Century: Will *In Vivo* Studies Become Obsolete?" will be offered on Sunday before the general sessions begin. There is no extra fee to attend the career development program. The Career Development Luncheon Series "Interacting with Our MD Colleagues" will take place on Monday and will be open to all. There is no extra fee to attend the Luncheon Series, however, registration is required.

The Exhibit Hall is always an important part of our meeting, and I encourage you to visit all of the exhibitors in their booths. The exhibitors will again sponsor a Monday buffet lunch in the hall for all symposium attendees.

STP Special Interest Groups (SIGs) have scheduled meetings during the week. All are open to members and interested nonmember attendees. Please check the Registration Desk for meeting times and locations for: Clinical Pathology, Neuropathology, Reproductive Toxicologic Pathology, Environmental Toxicologic Pathology, Cardiovascular Pathology, and Medical Device Pathology.

June is a wonderful time to visit sunny San Diego. Tuesday will again be a free afternoon for attendees, and I encourage you to explore San Diego's many attractions, quite a few of which are walking distance from the hotel. The San Diego Metro Trolley Green Line stops nearby and makes even more of San Diego accessible.

I look forward to meeting you during the week and at the President's Reception on Wednesday evening following the Awards Ceremony and Annual Business Meeting. Enjoy the meeting and thank you for your participation!!

Sincerely,



Kenneth A. Schafer, DVM, PhD, DACVP, FIATP  
STP President

## Executive Committee

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### **STP President: Kenneth A. Schafer, DVM, PhD, DACVP, FIATP**

Vet Path Services, Inc.

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Bristol Myers Squibb Company

#### **John Michael Cullen, VMD, PhD, DACVP**

North Carolina State University

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Michigan State University

#### **John L. Vahle, DVM, PhD, DACVP**

Eli Lilly & Company

#### **Douglas C. Wolf, DVM, PhD, ATS, FIATP**

Syngenta

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(NTP Symposium Liaison) NTP/NIEHS

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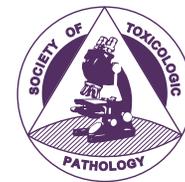
#### **William Siska, DVM, MS, DACVP**

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#### **Thomas Steinbach, DVM, DACVP, DABT**

EPL, Inc.

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To reduce paper usage and to provide premeeting access to information, speaker and poster abstracts, the attendee list, session evaluations, and links to meeting-related surveys are all online. Please visit [www.toxpath.org/am2016/materials.asp](http://www.toxpath.org/am2016/materials.asp).

You will be prompted for a login. Members can access with normal STP login. Other attendees can access with login provided via email.

## 2016 STP Lifetime Achievement Award Recipient

**Dianne M. Creasy, PhD, Dip RCPATH (tox), FRCPath**



The Society of Toxicologic Pathology honors Dianne M. Creasy, PhD, Dip RCPATH (tox), FRCPath as co-recipient of the 2016 STP Lifetime Achievement Award.

Dr. Creasy presently provides consultancy advice through her own company, Dianne Creasy Consulting LLC, on all aspects of toxicologic pathology including interpretation and assessment of issues involving male or female reproductive toxicology. Prior to this she spent over 15 years with Huntingdon Life Sciences (now Envigo) at East Millstone, New Jersey serving as Director of Pathology and latterly as Senior Scientific Advisor and Consultant Pathologist. Prior to moving to the US in 1999 from the UK, Dr. Creasy's esteemed career includes working as Principal Scientist, at Shell Research Ltd, Kent, and Research Scientist at the British Institute of Biological Research Association, Surrey, having started her career as a histology technician and pathologist at Wellcome Research Labs in Kent. She received her PhD in 1987 from University College, University of London and gained board certification by examination in toxicologic pathology from the Royal College of Pathologists in 1991.

An internationally recognized expert on male reproductive pathology, Dr. Creasy's primary interest and expertise in the male reproductive system has grown to also include the female reproductive system. She has conducted and published research on reproductive pathology throughout her long and productive career. Her most significant contributions to the literature have focused on toxicity of the male reproductive system, endocrine disruption and stress responses. She has authored nine book chapters and more than 65 journal articles published in such leading journals as *Toxicologic Pathology*, *Journal of Pathology*, *Experimental and Molecular Pathology*, *Toxicology and Applied Pharmacology*, *Reproductive Toxicology*, and *Veterinary Pathology*. Her co-authored chapter on the male reproductive system has appeared in every edition of *Haschek and Rousseaux's Handbook of Toxicologic Pathology*, one of the classic references in the field.

A member of the Society of Toxicologic Pathology since 1998, Dr. Creasy has served as a Councilor on the Executive Committee (2010–2014) and as a member of the Education Committee, several subcommittees and multiple working groups including: INHAND Apoptosis/Necrosis (Chair), Male Reproductive System (Chair), Endocrinology Endpoints, and Prepubertal Assays for EPA. She has also served on the editorial boards of *Toxicologic Pathology*, *Toxicological Sciences*, and *Birth Defects Research* and is regularly invited to review articles for many other international journals. As a result of her research, publications and advocacy, Dr. Creasy's scientific work has had a major impact on the assessment and interpretation of toxic effects on the male reproductive system. Internationally recognized as a public speaker and teacher, she has presented lectures and workshops throughout the United States and in Britain, France, Switzerland, Germany, Belgium, Japan, China, Brazil, Colombia, and India. She is particularly well known for giving multiple day workshops on Evaluating the Male and Female Reproductive Systems for Toxicity. In these workshops, she skillfully guides participants through the histological complexities of the testes and epididymides and then challenges them to use their knowledge to interpret toxic changes. Pathologists all over the world cite Dr. Creasy's lectures as the basis of their understanding of the male reproductive system.

In consideration of the breadth and depth of her lifetime contributions to science, to her fellow pathologists, to regulators and to the STP, the Society of Toxicologic Pathology is pleased to recognize Dianne M. Creasy as a recipient of the 2016 STP Lifetime Achievement Award.

## 2016 STP Lifetime Achievement Award Recipient

**Robert H. Garman, DVM, DACVP**



The Society of Toxicologic Pathology is proud to honor Dr. Robert H. Garman, DVM, DACVP as co-recipient of the 2016 STP Lifetime Achievement Award.

Over the years, Dr. Garman has had a major impact on regulatory neuropathology. He has had more than 40 years of experience in veterinary and comparative pathology and has been specializing in neuropathology for over 20 years. Over his professional career, he has held a variety of positions in government, academia, and industry but, for the majority of his career, has been a self-employed consulting pathologist. While serving in the Public Health Service at the NIH in the late 60s, Dr. Garman made the decision to pursue pathology as a profession. Wanting to take a comparative approach, he decided to pursue this training at a medical school. After receiving residency training in pathology at the University of Rochester School of Medicine and Dentistry, he joined the pathology department faculty there and started to develop a subspecialty in neuropathology by collaborating with scientists who were studying animal models of alkylmercurial encephalopathy. After 10 years at

the University of Rochester, Dr. Garman accepted a position at the Bushy Run Research Center (a contract laboratory run by Carnegie Mellon University in Pittsburgh, Pennsylvania), making this move in order to gain additional experience in toxicologic pathology. After a decade performing histopathologic evaluations on a wide spectrum of rodent studies, he decided to become a self-employed consultant in order to have the freedom to once again collaborate with investigators studying various forms of brain injury. Although this step was financially risky, it was also a time when the US EPA and later the OECD were developing new guidelines for both general neurotoxicity and developmental neurotoxicity studies. In order to perform these studies, specialized neuropathologic staining and dissection techniques needed to be improved upon, and it was his wife, Rosalyn, who set up a histology lab, trained technicians and refined these techniques.

Over the decades, Dr. Garman's primary focus has been to detect potential neurotoxic effects of drugs and chemicals. However, in addition to serving as either a primary or peer-review pathologist on a wide variety of neurotoxicity studies, he currently provides collaborative neuropathology support to various investigators at the University of Pittsburgh who are studying models of brain injury. Dr. Garman currently holds adjunct appointments in both the University of Pittsburgh's Neuropathology Division and within the Safar Center for Resuscitation Research, and he very much enjoys sharing his knowledge with investigators at these institutions, as well as at scientific meetings and symposia such as those conducted by the STP, ESTP, and BSTP. His colleagues have reported him to be a highly effective teacher who, via his vast assortment of photomicrographs, is able to engender enthusiasm for the histological study of neurologic disease.

Dr. Garman received his BS in Animal Physiology in 1963 and DVM in 1966 from Cornell University. Following a year of private veterinary practice and a tour of duty with the USPHS, he continued his studies in pathology at the University of Rochester School of Medicine and Dentistry from 1969–1971, subsequently serving as a faculty member in the Departments of Pathology and of Laboratory Animal Medicine from 1971–1978. From 1978–1988, he served as a Research Pathologist at the Bushy Run Research Center prior to establishing Consultants in Veterinary Medicine, Inc. in 1988.

A member of the Society of Toxicologic Pathology since the 80s, Dr. Garman is a contributing member of multiple STP Working Groups, including INHAND Central Nervous System, CNS Sampling, PEGylation, and Peripheral Nervous System (PNS). Based on a lifetime of significant achievement and continued contributions to the field of toxicologic pathology, the STP is pleased to recognize Dr. Garman as a 2016 Lifetime Achievement Awardee.

## 2016 STP Distinguished Early Career Award Recipient

Michael C. Boyle, DVM, PhD, DACVP, DABT



For his current contributions to the pharmaceutical industry, important work in academic and governmental sectors, outstanding knowledge and skills as a toxicologic pathologist and toxicologist, and creativity as a biomedical researcher, the Society of Toxicologic Pathology recognizes Michael C. Boyle, DVM, PhD, DACVP, DABT as the 2016 STP Distinguished Early Career Awardee.

Dr. Boyle received his BS (2004) and DVM (2006) from Michigan State University, and PhD (2014) from North Carolina State University. He completed residency training in toxicologic and anatomic pathology at MPI Research and Michigan State University in 2009 and became an ACVP Diplomat the same year. In 2013, he was certified in General Toxicology by the American Board of Toxicologists.

Currently Principal Pathologist and Nonclinical Safety Sciences Lead at Amgen, Inc. in Thousand Oaks, California, Dr. Boyle manages the nonclinical strategies of molecules in the cardiovascular and inflammation fields, and is the pathologist for a variety of programs throughout the Cardiometabolic, Inflammation, Immuno-Oncology, and Neuroscience therapeutic areas. He is also a Scientific Member of the IACUC.

Through his publication record and numerous invited presentations, Dr. Boyle has particularly distinguished himself in the cardiovascular arena. Prior to joining Amgen, Inc. Dr. Boyle completed a toxicologic pathology postdoctoral fellowship (2009–2013) with the National Toxicology Program (NTP), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), Research Triangle Park, North Carolina. As a graduate student in Dr. Trevor Archer's laboratory, he studied epigenetics and the chromatin-remodeling enzyme, *Brg1*. By developing an *in vivo* translational model within an *in vitro* laboratory, he expanded the team's capabilities while identifying a potential therapeutic target to ameliorate anthracycline chemotherapy-related cardiotoxicity. Under Dr. David Malarkey, his postdoctoral fellowship mentor, Dr. Boyle worked as a laboratory animal pathologist and collaborator for the NIEHS vivarium and was responsible for overseeing pathology assessment of subchronic and chronic toxicity and carcinogenicity rodent bioassays, participating in pathology peer reviews and pathology working groups, and contributing to the compilation and authorship of NTP Technical Reports.

Dr. Boyle has already shown a strong dedication to the field of toxicologic pathology as a mentor and leader. He's a member of the Predictive Safety Testing Consortium, and has been an invited panelist and advisor at the NIEHS' Biomedical Career Symposium and the ACVP's Certifying Examination Standard Setting Group. He has been a speaker for the American College of Toxicology's Pathology for Non-Pathologists course and served as the Society of Toxicology's Postdoctoral Representative for the Regulatory and Safety Evaluation and Cardiovascular Toxicology Specialty Sections. As an STP member, he has been active in the promotion and support of the Society, as chair and member of multiple committees, including the Joint Education Based Committee, Internet Committee (Chair), ToxPath.org Subcommittee (Chair), Career Development and Outreach Committee, INHAND Cardiovascular Working Group, INHAND Bones, Joints and Teeth Working Group, Annual Meeting CE session (Co-Chair), and 2017 Scientific Program Planning Committee (Co-Chair). In addition to editorial duties at *Toxicological Sciences*, *Veterinary Pathology*, and the *Journal of the American Veterinary Medical Association*, he is on the Editorial Board for *Toxicologic Pathology*. He has been the recipient of several honors, including NIH Intramural Research Training Awards and an STP Young Investigator Award. For his exceptional early career accomplishments in toxicologic pathology, Michael C. Boyle is awarded the 2016 STP Distinguished Early Career Award.

## ● Toxicologic Pathology Best Paper Awards

### Best Paper Award for Original Manuscript

#### Chimeric Mice with Hepatocyte-Humanized Liver As an Appropriate Model to Study Human Peroxisome Proliferator-Activated Receptor- $\alpha$

*Toxicol Pathol*, 2015; 43(2): pp. 233–248, originally published online August 8, 2014.

Chise Tateno<sup>1,2,3</sup>, Toshinobu Yamamoto<sup>4</sup>, Rie U<sup>1,5,4</sup>, Chihiro Yamasaki<sup>4,1,3</sup>, Yuji Ishida<sup>2,3</sup>, Yuka Myoken<sup>6,1,2,3,8</sup>, Ken Oofusa<sup>6,7</sup>, Miyoko Okada<sup>4</sup>, Naohisa Tsutsui<sup>4</sup>, and Katsutoshi Yoshizato<sup>1,2,3,8</sup>

<sup>1</sup>Yoshizato Project, Cooperative Link of Unique Science and Technology for Economy Revitalization (CLUSTER), Hiroshima Prefectural Institute of Industrial Science and Technology, Higashihiroshima, Japan, <sup>2</sup>Liver Research Project Center, Hiroshima University, Hiroshima, Japan, <sup>3</sup>PhoenixBio Co., Ltd., Higashihiroshima, Japan, <sup>4</sup>Safety Research Laboratory, Mitsubishi Tanabe Pharma Corporation, Kisarazu, Japan, <sup>5</sup>Institute of Advanced Biomedical Engineering and Science, Tokyo Women's Medical University, Tokyo, Japan, <sup>6</sup>Prophoenix Co., Ltd., Developmental Biology Laboratory, Higashihiroshima, Japan, <sup>7</sup>Prophoenix Division, Idea Consultants, Osaka, Japan, <sup>8</sup>Hiroshima University 21st Century COE Program for Advanced Radiation Casualty Medicine, Department of Biological Science, Graduate School of Science, Hiroshima University, Higashihiroshima, Japan

### Best Paper Award for Invited Review/Review

#### Nonlesions, Misdiagnoses, Missed Diagnoses, and Other Interpretive Challenges in Fish Histopathology Studies

##### A Guide for Investigators, Authors, Reviewers, and Readers

*Toxicol Pathol*, 2015; 43(3): pp. 297–325, originally published online August 11, 2014.

Jeffrey C. Wolf<sup>1</sup>, Wes A. Baumgartner<sup>2</sup>, Vicki S. Blazer<sup>3</sup>, Alvin C. Camus<sup>4</sup>, Jeffery A. Engelhardt<sup>5</sup>, John W. Fournie<sup>6</sup>, Salvatore Frasca Jr<sup>7</sup>, David B. Groman<sup>8</sup>, Michael L. Kent<sup>9</sup>, Lester H. Khoo<sup>10</sup>, Jerry M. Law<sup>11</sup>, Eric D. Lombardini<sup>12</sup>, Christine Ruehl-Fehler<sup>13</sup>, Helmut E. Segner<sup>14</sup>, Stephen A. Smith<sup>15</sup>, Jan M. Spitsbergen<sup>16</sup>, Klaus Weber<sup>17</sup>, Marilyn J. Wolfe<sup>1</sup>

<sup>1</sup>Experimental Pathology Laboratories, Inc., Sterling, Virginia, USA, <sup>2</sup>Department of Pathobiology/Population Medicine, College of Veterinary Medicine, Mississippi, USA, <sup>3</sup>US Geological Survey, Kearneysville, West Virginia, USA, <sup>4</sup>Department of Pathology, College of Veterinary Medicine, University of Georgia, Athens, Georgia, USA, <sup>5</sup>Experimental Pathology Laboratories, Inc., Camarillo, California, USA, <sup>6</sup>US Environmental Protection Agency, National Health and Environmental Effects Research Laboratory, Gulf Ecology Division, Gulf Breeze, Florida, USA, <sup>7</sup>Connecticut Veterinary Medical Diagnostic Laboratory, Department of Pathobiology and Veterinary Science, University of Connecticut, Storrs, Connecticut, USA, <sup>8</sup>Aquatic Diagnostic Services, Atlantic Veterinary College, University of Prince Edward Island, Charlottetown, Prince Edward Island, Canada, <sup>9</sup>Departments Microbiology and Biomedical Sciences, Oregon State University, Corvallis, Oregon, USA, <sup>10</sup>Mississippi State University, College of Veterinary Medicine, Stoneville, Mississippi, USA, <sup>11</sup>Aquatic Ecotoxicology, North Carolina State University College of Veterinary Medicine, Raleigh, North Carolina, USA, <sup>12</sup>Divisions of Comparative Pathology and Veterinary Medical Research Department of Veterinary Medicine, Armed Forces Research Institute of Medical Sciences (AFRIMS), Bangkok, Thailand, <sup>13</sup>Bayer HealthCare AG, Wuppertal, Germany, <sup>14</sup>Centre for Fish and Wildlife Health, University of Bern, Bern, Switzerland, <sup>15</sup>Virginia-Maryland Regional College of Veterinary Medicine, Virginia Tech, Blacksburg, Virginia, USA, <sup>16</sup>Fish Disease Research Group, Department of Microbiology, Oregon State University, Corvallis, Oregon, USA, <sup>17</sup>AnaPath GmbH, Oberbuchsitzen, Switzerland

## ● Society of Toxicologic Pathology Student Travel Awards

### Elizabeth Clark

The Ohio State University

### Evan Frank

University of Cincinnati

### Sonika Patial

Louisiana State University

### Fuyuan Wang

Cornell University

### Said Elshafae

The Ohio State University

### Bonnie Harrington

The Ohio State University

### Leah Stein

Michigan State University

### Miaofei Xu

National Toxicology Program/  
NIEHS

### Jessica Fortin

University of Missouri

### Craig Miller

Colorado State University

## ● Society of Toxicologic Pathology Student Poster Award

### Lydia Ansen-Wilson

University of Wisconsin School of Veterinary Medicine

We would like to congratulate Lydia Ansen-Wilson, BS, for winning the 2016 STP Student Poster Award for her poster entitled, "Pathogenesis of Forebrain Abnormalities in a Teratogen-Induced Model of Orofacial Clefting." The Tenth Annual STP Student Poster Award competition occurred during the 2015 ACVP|ASVCP|STP Combined Meeting held in Minneapolis, Minnesota, October 17–21, 2015. The poster presentations were evaluated by a panel of judges composed of members of the Society of Toxicologic Pathology and the American College of Veterinary Pathology.

## ● IATP Charles Capen Trainee Award

### Fuyuan Wang

University of Minnesota

## ● Society of Toxicologic Pathology Young Investigator Awards

(See pages 9 or 22 for judging times.)

Winners will be announced at the Awards Ceremony at 5:30 pm on Wednesday, June 29, in Grand Hall A.

## Meeting Events

### Welcome Reception

Sunday, June 26, 5:30 PM–7:00 PM

#### Grand Hall C

The STP Welcome Reception will kick off the week in the Exhibit Hall for all registered meeting attendees. Please wear your badge and bring your Welcome Reception ticket that was provided with your badge. Drink tickets will be distributed at the door. Tickets for guests 18 years of age or older\* accompanying a registered attendee may be purchased for \$30 at the registration desk.

*\*To ensure their safety, children under the age of 18 are not permitted in the Exhibit Hall.*

### Student/Mentor Mixer

*Sponsored by EPL, Inc. and Envigo*

*Registration Required*

Sunday, June 26, 7:00 PM–8:30 PM

#### Torrey Hills A

Light snacks and drink tickets will be provided.

### Lunch in the Exhibit Hall

Monday, June 27, 12:00 Noon–1:30 PM

#### Grand Hall C

Lunch sponsored by the exhibitors for all scientific attendees.

### Student Outing

*Sponsored by EPL, Inc. and Envigo*

Tuesday, June 28, 12:15 PM

#### Hillcrest A

The STP Student Outing will be teaming up with R&D Events to engage in some friendly competition as we divide and conquer to compete in a Snapshot Photo Challenge in Seaport Village. Lunch will be served prior to the outing with dessert immediately following in Hillcrest A.

### Awards Ceremony

Wednesday, June 29, 5:30 PM–5:50 PM

#### Grand Hall A

STP Award recipients will be recognized at this time.

### Annual Business Meeting

Wednesday, June 29, 5:50 PM–6:30 PM

#### Grand Hall A

The STP Annual Business Meeting will be held immediately following the Awards Ceremony.

### President's Reception

Wednesday, June 29, 7:00 PM–9:00 PM

#### Grand Hall C

One ticket to this event is provided to all meeting registrants. Please wear your badge and bring your President's Reception ticket that was provided with your badge. Drink tickets will be distributed at the door. Additional tickets can be purchased on-site for \$65 (Children of attendees 11–17 years \$35). Attendees with children under 11 years of age are permitted to attend the President's Reception at no charge as long as the child is under the supervision of the parent at all times.

*All events are in the Manchester Grand Hyatt unless otherwise indicated.*

## Headquarters Hotel

### Manchester Grand Hyatt San Diego

Hyatt San Diego

1 Market Place

San Diego, California, USA 92101

Tel: 619-232-1234



### WiFi Options of Manchester Grand Hyatt

#### Complimentary WiFi

Available complimentary in the public spaces of the hotel.

Complimentary wireless internet is also offered in all Guest Rooms.

## Registration

### Grand Hall Foyer

Friday, June 24 ..... 4:00 PM–6:00 PM

Saturday, June 25 ..... 8:00 AM–6:00 PM

Sunday, June 26 ..... 7:00 AM–6:00 PM

Monday, June 27 ..... 7:00 AM–5:30 PM

Tuesday, June 28 ..... 7:00 AM–12:00 Noon

Wednesday, June 29 ..... 7:30 AM–5:30 PM

Thursday, June 30 ..... 7:30 AM–12:00 Noon

### Registration Materials

Badges, Program, event tickets, and ribbons (if appropriate), will be available for pick up at the Registration Desk (see registration hours above). Attendees are encouraged to bring a bag or backpack as meeting bags will not be provided.

### Meeting Materials

Meeting publications, handouts, attendee list, committee and ancillary meetings schedule, and evaluation forms will be posted on the Annual Meeting "Meeting Materials" page when available. STP members will use their regular login to access this page. Nonmember attendees will receive login and password via email to access the website.

### Symposium Registration

Member, Nonmember, and Student full meeting registration fee include the symposium proceedings, access to scientific sessions, Exhibit Hall, morning and afternoon breaks during the scientific sessions, Monday lunch in the Exhibit Hall, and admission for one to the Welcome Reception and President's Reception.

### Exhibitor Registration

**Complimentary:** Two full meeting registrations are provided to exhibiting companies with the purchase of each booth. The Exhibitor registration fee includes admission to the scientific sessions, Exhibit Hall access, afternoon breaks, Monday lunch held in the Exhibit Hall, and admission for one to the Welcome Reception and President's Reception.

**Reduced Registration:** The Exhibitor registration fee (\$380) is for companies with more than two exhibitors. This reduced registration does not include admission to the scientific sessions, but does include breaks in the Exhibit Hall, and one admission to the Welcome Reception and President's Reception.

### Guest Registration

The Guest registration fee includes one admission to the Welcome Reception (Sunday) and the President's Reception (Wednesday).

**SPECIAL MEMBERSHIP OFFER:** Nonmembers who apply for membership prior to July 1 and who are accepted will receive complimentary membership for the remainder of 2016 and the online journal issues for the remainder of the year. Please visit [www.toxpath.org](http://www.toxpath.org) to apply for membership.

## Speaker Ready Room

### Bankers Hill, 3rd Floor

Saturday, June 25 .....	8:00 AM–5:00 PM
Sunday, June 26.....	7:00 AM–5:00 PM
Monday, June 27 .....	7:00 AM–5:00 PM
Tuesday, June 28 .....	7:00 AM–12:00 Noon
Wednesday, June 29 .....	7:00 AM–5:00 PM
Thursday, June 30.....	7:00 AM–11:00 AM

## Poster Information

### Grand Hall C

The poster board size is 4' x 8' (horizontal) and requires the use of pushpins to hold it in place.

### Poster setup and teardown times are as follows:

#### Poster Setup

Sunday, June 26 .....

8:00 AM–3:00 PM
-----------------

Your poster must be set up by 3:00 pm on Sunday, June 26.

#### Poster Teardown

Wednesday, June 29 .....

11:30 AM–1:00 PM
------------------

If your poster is not removed before 1:00 pm on Wednesday, June 29, it will be removed and placed near the Registration Desk for pick up.

#### Poster Presentation Times

Please plan to attend your posters during the following times:

Sunday, June 26 .....	6:00 PM–6:30 PM
Monday, June 27 .....	9:55 AM–10:25 AM
.....and 3:20 PM–3:50 PM	
Tuesday, June 28 .....	9:20 AM–10:00 AM
Wednesday, June 29 .....	10:05 AM–10:40 AM

### Young Investigator Judging Times

Monday, June 27 .....	7:15 AM–8:00 AM
.....	10:30 AM–11:00 AM
.....and 3:00 PM–3:35 PM	
Tuesday, June 28 .....	9:45 AM–10:20 AM

## Exhibit Hall

### Grand Hall C

The Exhibit Hall will be a center of activity during this year's Symposium, kicking off with a Welcome Reception in the Exhibit Hall on Sunday evening, June 26.

A sponsored buffet luncheon in the Exhibit Hall will be offered for all registered attendees on Monday, June 27, and morning and afternoon refreshment breaks will be held in the hall throughout the week unless otherwise noted. Scientific poster sessions will also be held Sunday evening through Wednesday in the Exhibit Hall.

The Society values the support of exhibitors and believes the relationship between exhibiting companies and the STP membership is a mutually beneficial one. Don't forget to visit the Grand Hall C.

### Exhibit Hall Policies

Out of courtesy for the scientific presenters and exhibitors, we appreciate your compliance with the following policies:

#### Photography Policy

- Photography of poster presentations is prohibited without the specific consent of the presenter(s)/author(s).
- Photography of exhibitor booths and/or equipment is prohibited without the specific consent of the exhibitor.

#### Children Under 18 Years of Age

- To ensure their safety, children under the age of 18 are not permitted in the Exhibit Hall at any time including during the Exhibits Opening, regular hours, Welcome Reception, and Poster Sessions.

### Exhibitor Setup

Saturday, June 25 .....	1:00 PM–4:00 PM
Sunday, June 26.....	8:00 AM–3:00 PM

*All exhibits must be set up by 3:00 PM*

### Exhibit Hall Hours

Sunday, June 26 (Welcome Reception) .....	5:30 PM–7:00 PM
Monday, June 27 .....	9:00 AM–4:00 PM
Tuesday, June 28 .....	9:00 AM–12:00 Noon
Wednesday, June 29 .....	9:00 AM–11:30 AM

### Exhibitor Teardown

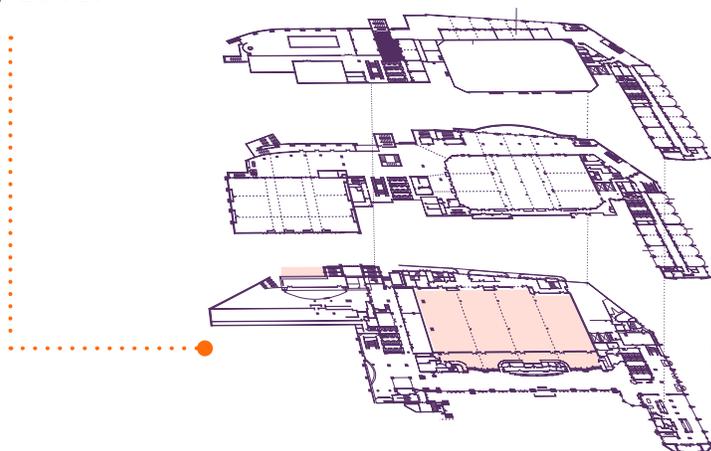
Wednesday, June 29 .....	11:30 AM–3:00 PM
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## Safety and Security Tips

1. When inside the conference venue, nametags should be worn and visibly displayed at all times. For security reasons, we recommend that you DO NOT wear your badge outside of the conference venue. If you lose your badge, please notify registration immediately.
2. Walk in well-lighted areas at night and never alone.
3. Please do not leave any bags or articles unsecured in any display area, meeting room, or public area. Laptops and other small computers are easy targets for thieves. If you note any suspicious articles, packages, persons, or activity please contact the event staff or security immediately.
4. Due to the nature of our meeting, there is a risk that we may be the target of protest activity. STP has a response plan to address this possibility. Here are some guidelines to deal with protest activity:
  - a. If you see a protest forming or in progress, you should notify STP or venue staff immediately. We will implement our response plan to ensure our meeting is safe and secure.
  - b. Do not attempt to engage or argue with protestors. These groups seek confrontation as a tool for publicity.
  - c. Do not give interviews to press personnel. STP representatives will respond to the press.
  - d. If you notice any suspicious individuals in the meeting areas or hotel, especially handing out literature, please notify STP security or venue security personnel. You should not attempt to engage these persons or stop them yourself
  - e. If there is a disruption in a meeting room, you should remain calm. Notify security and allow them to deal with the disruption.
5. Do not give your lodging information to any person outside of known STP staff.
6. Photography is not permitted in the Exhibit Hall. This includes digital pictures taken using cell phone cameras.
7. Large packages and bags are not permitted in the Exhibit Hall area.

## Manchester Grand Hyatt Maps

### Lobby Level



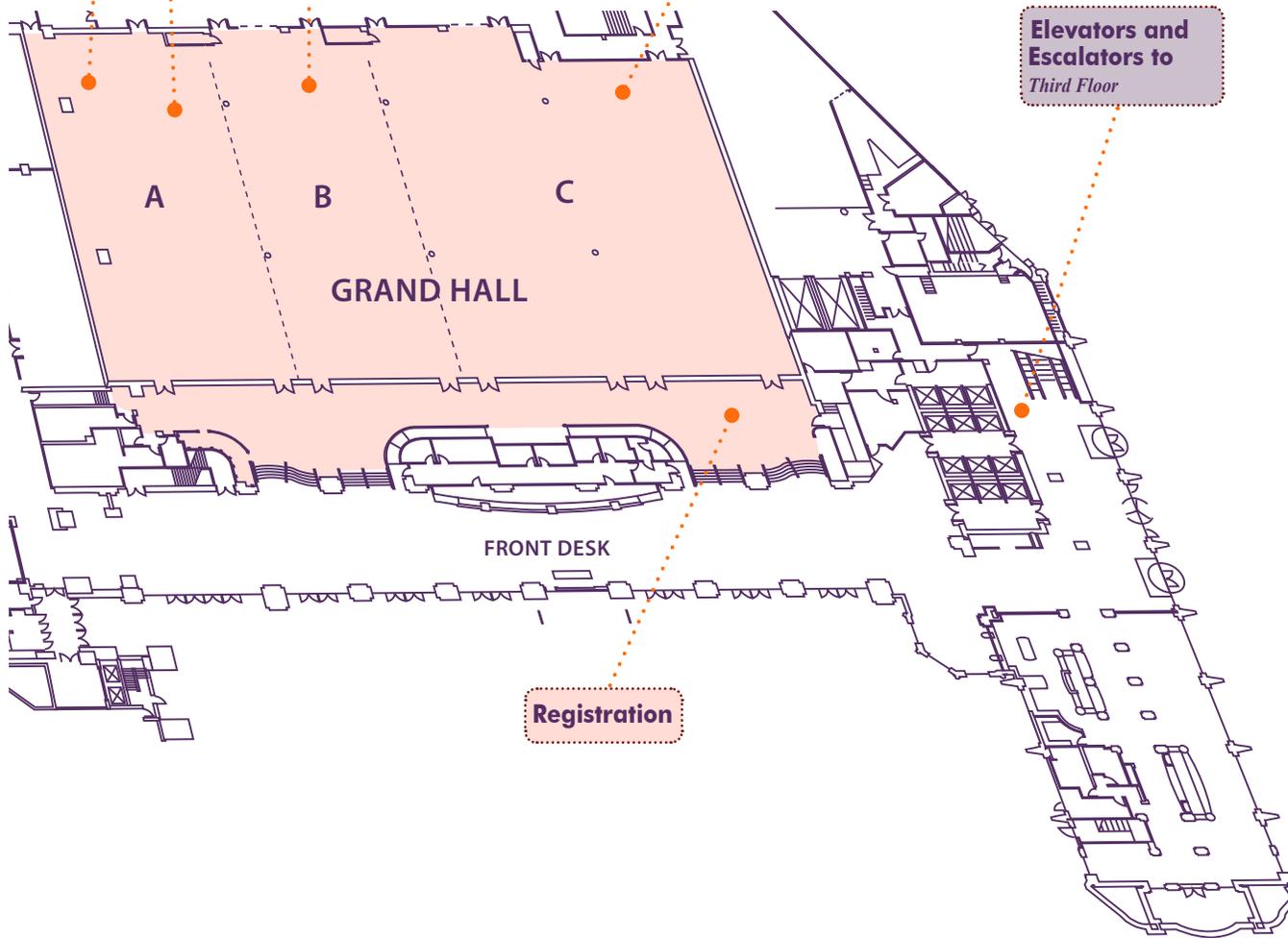
**NTP Satellite Symposium**  
Scientific Sessions  
Awards Ceremony

CE1  
CE3

CE2  
CE4

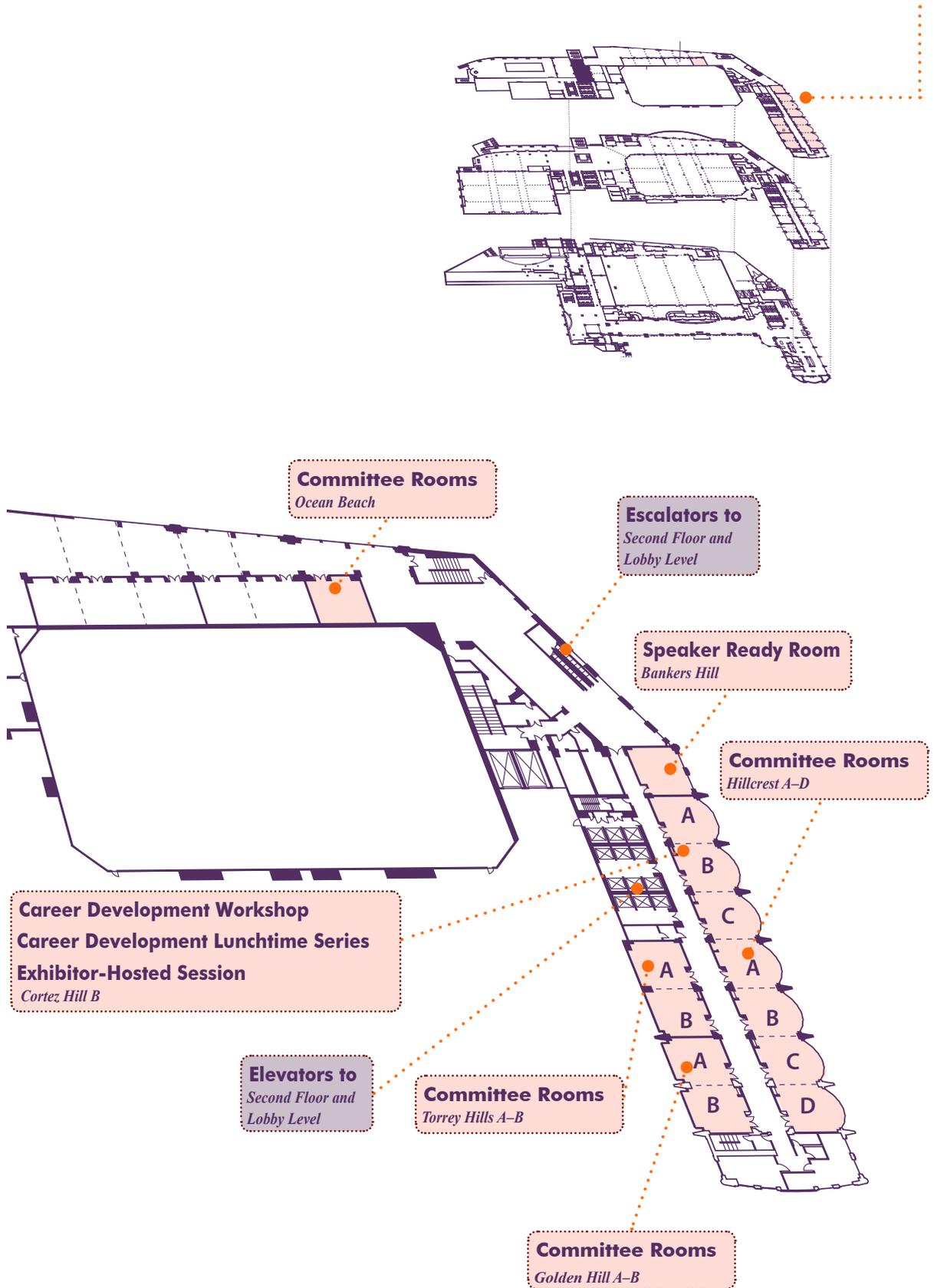
**Welcome Reception**  
President's Reception  
Exhibits and Posters

**Elevators and Escalators to  
Third Floor**



# Manchester Grand Hyatt Maps

## Third Level



# SAN DIEGO

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Society of Toxicologic Pathology

Founded 1971  
Membership 1,250

Be an international leader for improvement of human, animal, and environmental health using an interdisciplinary scientific approach based in pathology and toxicology.

### SPECIAL MEMBERSHIP OFFER:

Nonmember registrants who apply for membership prior to **July 1** and who are accepted, will receive complimentary Membership for the rest of 2016 and the online journal issues for the remainder of the year.

## What Are the Benefits of STP Membership?



### Publications

- Society's journal, *Toxicologic Pathology* (online)
- Online *Scope* Newsletter



### Member Access

- **ToxPathNet** —Member Network
- ToxPath Newsgroup
- Early Drafts of Position Papers
- Full-Text Articles from *Toxicologic Pathology*
- STP Business Activities
- STP Membership Directory
- Surveys Conducted by the Scientific and Regulatory Policy Committee
- Career Surveys
- Presentations on Toxicologic Pathology for Nonpathologists (Regulators, Toxicologists, and Students)
- STP Special Interest Groups
- CE Courses and Selected Presentations



### Collaboration

- Annual Symposium
- Committees
- Regional Meetings
- Working Groups
- Other Activities



### Education

- Continuing Education
- Modular Education Course
- Regional Meetings
- Webinars



### Groups

- Special Interest Groups
  - Cardiovascular Toxicologic Pathology
  - Clinical Pathology
  - Environmental Toxicologic Pathology
  - Medical Devices Special Interest Group
  - Neuropathology
  - Reproductive Pathology

## Join Today

### Fast and Easy Online Membership Application

To learn more about STP activities visit [www.toxpath.org](http://www.toxpath.org). To apply online, select Membership Application from the navigation bar. Students are invited to apply for Student Membership.

[www.toxpath.org](http://www.toxpath.org)

## Saturday, June 25

### NTP Satellite Symposium: Pathology Potpourri

9:00 AM–4:30 PM

Grand Hall A

*Chair: Susan A. Elmore, MS, DVM, DABT, FIATP, DACVP, NTP and NIEHS, Research Triangle Park, NC*

The object of this interactive symposium is to provide continuing education on interpreting pathology slides, to generate lively and productive conversation, and to have a good time. During each talk, the speakers will project a series of images of lesions on one screen with a choice of diagnoses/answers on a separate screen. The members of the audience will then vote using wireless keypads and the results will be displayed on the screen. Time is allowed for discussion after each voting session.

9:00 AM–9:10 AM

#### Welcome and Introductory Remarks

*Susan A. Elmore, MS, DVM, DACVP, DABT, FIATP, National Toxicology Program, NIEHS, Research Triangle Park, NC*

9:10 AM–9:30 AM

#### Use Your Noggin'

*David E. Malarkey, DVM, PhD, DACVP, FIATP, National Toxicology Program, NIEHS, Research Triangle Park, NC*

9:30 AM–10:00 AM

#### RSCABS: Picking at Histopathology Data

*Jeffrey C. Wolf, DVM, DACVP, Experimental Pathology Laboratories, Inc., Sterling, VA*

10:00 AM–10:30 AM

#### Thinking Thinking!

*Gabrielle A. Willson, BVMS, FRC Path, Experimental Pathology Laboratories, Inc., Durham, NC*

10:30 AM–11:00 AM

#### Break

11:00 AM–11:30 AM

#### Maybe Not a No-Brainer

*Linda Kooistra, DVM, PhD, DACVP, Charles River Laboratories, Inc., Durham, NC*

11:30 AM–12:00 Noon

#### Getting to the Heart of the Matter

*Susan A. Elmore, MS, DVM, DACVP, DABT, FIATP, National Toxicology Program, NIEHS, Research Triangle Park, NC*

12:00 Noon–1:30 PM

#### Lunch

1:30 PM–1:50 PM

#### An Axillary Anomaly

*Vivian S. Chen, DVM, PhD, DACVP, National Toxicology Program, NIEHS, Research Triangle Park, NC*

1:50 PM–2:10 PM

#### Challenging Cases or Run-of-the-Mill?

*Kathleen A. Szabo, DVM, MS, DACVP, Charles River Laboratories, Inc., Durham, NC*

2:10 PM–2:30 PM

#### Abnormal Fetal Development: Finding the Needle in a Gestational Sac

*Schantel Hayes-Bouknight, DVM, PhD, DACVP, Charles River Laboratories, Inc., Durham, NC*

2:30 PM–3:00 PM

#### Food for Thought

*Jessica Hoane, DVM, DACVP, Charles River Laboratories, Inc., Durham, NC*

3:00 PM–3:30 PM

#### Break

3:30 PM–3:50 PM

#### The Contralateral Mammary Gland: Missing the "Whole" Story

*Schantel Hayes-Bouknight, DVM, PhD, DACVP, Charles River Laboratories, Inc., Durham, NC*

3:50 PM–4:30 PM

#### Inhand Collaboration with US FDA on SEND

*Thomas Nolte, DVM, MSc, FIATP, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany*

### NTP Symposium Continuing Education Credits

#### AAVSB RACE Credits #56

The NTP Satellite Symposium is approved by the AAVSB RACE to offer a total of 5.00 CE Credits (5.00 max) being available to any one veterinarian: and/or 5.00 Veterinary Technician CE Credits (5.00 max). This RACE approval is for the subject matter category(s) of: Category One: Scientific using the delivery method(s) of: Seminar/Lecture. This approval is valid in jurisdictions which recognize AAVSB RACE; however, participants are responsible for ascertaining each board's CE requirements. Certificates of attendance will be provided at the conclusion of the NTP Satellite Symposium. Please contact the AAVSB RACE program if you have any comments/concerns regarding this program's validity or relevancy to the veterinary profession.

## Sunday, June 26

### Career Development Workshop

Sunday, June 26

8:00 AM–12:00 Noon

Cortez Hill B

Sponsored by EPL, Inc.

### Toxicity Testing in the 21st Century: Will In Vivo Studies Become Obsolete?

(Free Event, Registration Required)

Co-Chairs: *Erin M. Quist, DVM, MS, DACVP, EPL, Inc., Research Triangle Park, NC; and Kyathanahalli Janardhan, BVSc, MVSc, PhD, DACVP, Integrated Laboratory Systems, Research Triangle Park, NC*

There is a general perception that efforts such as Tox21 and other high-throughput screenings (HTS) will gradually replace *in vivo* animal testing. One of the major goals of HTS programs is to shift the reliance on animal testing for toxicological assessments of chemicals to variety of *in vitro* testing strategies that can be used by various agencies for hazard identification and regulation of

chemicals. While these efforts will certainly reduce time, cost, and animals involved in the regular rodent bioassays, it is justifiable to be skeptical about the success or reliability of such strategies given the complex nature of the biological system. To date, toxicologists seem to dominate the discussion on HTS strategies, and more involvement of pathologists is critical. The objective of this session is to provide a forum where we can discuss the pros and cons of HTS strategies from a pathologist's, toxicologist's, basic science researcher's, and regulatory agency's perspective.

8:00 AM–8:05 AM	<p><b>Introduction</b> <i>Erin M. Quist, DVM, MS, DACVP, EPL, Inc., Research Triangle Park, NC; and Kyathanahalli Janardhan, BVSc, MVSc, PhD, DACVP, Integrated Laboratory Systems, Research Triangle Park, NC</i></p>
8:05 AM–8:40 AM	<p><b>Tox21 and the Contribution of High-Throughput and High-Content Screening Assays to the National Toxicology Program</b> <i>Rick Paules, PhD, NIEHS/NTP, Research Triangle Park, NC</i></p>
8:40 AM–9:15 AM	<p><b>The Application of High-Density and High-Throughput Data for Prioritization- and Decision-Support for Crop Protection Chemicals</b> <i>Douglas C. Wolf, DVM, PhD, ATS, FIATP, Syngenta, Greensboro, NC</i></p>
9:15 AM–9:50 AM	<p><b>Tox 21 in the Rearview Mirror: Expectations vs. Scientific Realities</b> <i>Ram Ramabhadran, PhD, US EPA, Chapel Hill, NC</i></p>
10:00 AM–10:30 AM	<p><b>Break</b></p>
10:30 AM–11:05 AM	<p><b>Toxicologic Pathology in the Big Data Era (Is There an App for That?)</b> <i>Charles E. Wood, DVM, PhD, DACVP, US EPA, Research Triangle Park, NC</i></p>
11:05 AM–11:40 AM	<p><b>Tox21/HTS: Contemplating the Idea, Reality, and Future of Toxicology in the 21st Century at US FDA</b> <i>Sabine Francke, DVM, Dr. med. Vet., PhD, FIATP, US FDA/CFSAN, Silver Spring, MD</i></p>
11:40 AM–12:00 Noon	<p><b>Panel Discussion</b></p>

 **CE 1 (Sunday AM)**

8:00 AM–12:00 Noon

Grand Hall A

**The Respiratory System As a Target for Drug-Induced Toxicity: Pathology and Investigational Techniques**

*Co-Chairs: Nicholas Macri, DVM, MS, PhD, Envigo, East Millstone, NJ; and Kumar Changani, PhD, GlaxoSmithKline Pharmaceuticals, Stevenage, Hertfordshire, UK*

Safety assessment of inhaled therapeutics and chemicals, both industrial and environmental, requires detailed evaluation of the upper respiratory tract along with other standard protocol tissues. Regulatory agencies require the assessment of specific areas of the nasal cavity, larynx, trachea, and lungs in rodent and non-rodent animal models. Although histopathological changes in these organs are well-characterized in the literature, interpretation of their adversity and relevance to man are less clear-cut. The first half of this session will focus on methodologies used to deliver drugs by inhalation and the deposition patterns of inhaled drugs. Presentations on common background and test article-associated changes in different species, and comparative sensitivities of the upper respiratory tract, will cover the histopathological aspects of inhalation studies and their relevance to man. During the second half of the session, the importance of pulmonary macrophages in respiratory health and disease and models used in inhalation studies will be addressed. The final talk will focus on the use of imaging strategies for lung function. This will include MRI, CT, SPECT, PET, and optical modalities, which are being used in the pharmaceutical industry to understand disease in a longitudinal fashion. These modalities increase our understanding of drug delivery and allow discrimination of different aspects of lung pathology, including ventilation deficits, lung perfusion, pulmonary edema, cell migration, and fibrotic lesions.

8:00 AM–8:25 AM	<p><b>An Introduction to the Inhalation Study: Methods of Exposure and Tissue Processing</b> <i>Alison Rowles, BSc (Hons), BVMS (Hons), PhD, FRCPath, MRCVS, Envigo, Suffolk, UK</i></p>
8:25 AM–9:05 AM	<p><b>Common Background and Test Article-Associated Microscopic Changes in the Upper Respiratory Tract of Rodents and Dogs in Inhalation Studies</b> <i>Nicholas Macri, DVM, MS, PhD, Envigo, East Millstone, NJ</i></p>
9:05 AM–9:40 AM	<p><b>Comparative Sensitivities of the Upper Respiratory Tract in Laboratory Animals</b> <i>Vasanthi Mowat, BVSc, MVSc, MRCVS, FRCPath, Envigo, Alconbury, Cambridgeshire, UK</i></p>
9:40 AM–10:15 AM	<p><b>Break</b></p>
10:15 AM–10:50 AM	<p><b>Pulmonary Macrophages in Health and Disease</b> <i>Kristen J. Nikula, DVM, PhD, Seventh Wave Laboratories, Chesterfield, MO</i></p>
10:50 AM–11:20 AM	<p><b>Assessing and Interpreting Respiratory Function Endpoints in Toxicology Studies</b> <i>Ronald K. Wolff, PhD, DABT, RK Wolff – Safety Consulting, Inc., Carbondale, CO</i></p>
11:20 AM–12:00 Noon	<p><b>Imaging Strategies to Discriminate and Characterize Lung Pathology and Function</b> <i>Kumar Changani, PhD, GlaxoSmithKline Pharmaceuticals, Stevenage, Hertfordshire, UK</i></p>

## CE 2 (Sunday AM)

8:00 AM–12:00 Noon

Grand Hall B

### Interpreting and Integrating Clinical and Anatomic Pathology Results: Pulling It All Together

Sponsored by the American College of Toxicology (ACT)

**Co-Chairs:** *Mary Jane Hinrichs, PhD, MedImmune, LLC, Gaithersburg, MD; and Lila Ramaiah, DVM, PhD, DACVP, Envigo, East Millstone, NJ*

The interpretation of safety findings in toxicology studies requires an integrative weight of evidence approach that takes into account all collected data sets. Data must be evaluated in its entirety, as neither clinical nor anatomic pathology can be relied upon in isolation to fully understand the relationship between study findings and the test article. Basic principles for correlating anatomic pathology and clinical pathology findings and for integrating these with other study endpoints will be reviewed. A series of case examples, presented jointly by a clinical pathologist and an anatomic pathologist, will be used to illustrate the collaborative effort required between clinical and anatomic pathologists. In addition, the diagnostic utility of kidney and liver biomarkers will be discussed, based on data from meta-analyses of preclinical qualification and other studies. Examples of traditional and novel biomarker data implementation in nonclinical toxicology studies will also be presented to illustrate the relationship between discrete changes in biochemistry and tissue morphology in the real world drug development space.

8:00 AM–8:05 AM

#### Introduction

*Mary Jane Hinrichs, PhD, MedImmune, LLC, Gaithersburg, MD*

8:05 AM–8:55 AM

#### Principles for Correlating Anatomic Pathology and Clinical Pathology Findings in Toxicology Studies—Teasing Out Cause and Effect

*Lila Ramaiah, DVM, PhD, DACVP, Envigo, East Millstone, NJ*

8:55 AM–9:45 AM

#### Interpretation of Toxicity Findings through the Combination of Clinical and Anatomic Pathology Data (Part 1)

*Elizabeth V. Skuba, DVM, MVSc, DACVP, Novartis Pharmaceuticals, East Hanover, NJ*

9:45 AM–10:15 AM

#### Break

10:15 AM–11:05 AM

#### Interpretation of Toxicity Findings through the Combination of Clinical and Anatomic Pathology Data (Part 2)

*William O. Iverson, DVM, MedImmune, LLC, Faber, VA*

11:05 AM–11:55 AM

#### Evaluation and Implementation of Traditional and Non-Traditional Biomarkers of Kidney and Liver Injury

*Daniela Ennulat, DVM, PhD, GlaxoSmithKline, King of Prussia, PA*

11:55 AM–12:00 Noon

#### Questions and Discussion

## CE 3 (Sunday PM)

1:30 PM–5:30 PM

Grand Hall A

### Hematotoxicity and Immunotoxicity Assessment: Essential Principles and Emerging Modalities

**Co-Chairs:** *Bill Siska, DVM, MS, DACVP, Charles River Laboratories, Reno, NV; and Denise Bounous, DVM, PhD, DACVP, Bristol-Myers Squibb Company, Princeton, NJ*

Toxicity involving the hematopoietic system and lymphoid organs is frequently encountered in nonclinical safety studies and represents an important regulatory focus. Clinical pathology and anatomic pathology endpoints have traditionally been used for a first-line assessment of hematotoxicity and immunotoxicity, with additional specialized testing generally performed on a case-by-case basis consequent to study findings or in light of recognized drug class effects. As more specialized techniques including flow cytometry, functional assays, and other novel *in vitro* evaluations are increasingly utilized, it is important to understand the relationships between these modalities and traditional endpoints, and to be familiar with their advantages and limitations. This session will present comprehensive approaches to the evaluation of hematopoietic and lymphoid organ toxicity and will highlight correlations between non-traditional testing and routine endpoints through didactic presentations and integrated case examples.

1:30 PM–2:15 PM

#### Correlation Among Bone Marrow Cytology, Histopathology, and Hematology Data in the Assessment of Hematotoxicity in Nonclinical Studies: Principles and Case Examples

*Anne Provencher, DVM, MSc, DACVP, DECVCP, FIATP, Charles River Laboratories, Sherbrooke, Quebec, Canada*

2:15 PM–2:55 PM

#### Application of Flow Cytometry in Hematotoxicity Evaluation of Rodent Bone Marrow

*Cindy Zhang, BS, MS, Bristol Myers-Squibb Company, Princeton, NJ*

2:55 PM–3:25 PM

#### Break

3:25 PM–4:05 PM

#### Case Study of the Megakaryocyte Colony Forming Cell Assay As an *In Vitro* Model of Drug-Induced Thrombocytopenia

*Jacqueline Tarrant, BVSc, PhD, DACVP, Genentech, Inc., South San Francisco, CA*

4:05 PM–4:45 PM

#### Immunotoxicity: What the TDAR May Not Address

*Florence G. Burleson, PhD, Burleson Research Technologies, Inc., Morrisville, NC*

4:45 PM–5:30 PM

#### Immunotoxicity Assessment: One Size Does Not Fit All

*Ellen W. Evans, DVM, PhD, DACVP, Pfizer, Inc., Groton, CT*

 **CE 4 (Sunday PM)**

1:30 PM–5:30 PM

Grand Hall B

**Is It Adverse, Adaptive, Artifact?**

*Co-Chairs: Thomas Steinbach, DVM, DACVP, DABT, EPL, Inc., Durham, NC; and Arun Pandiri, BVSc&AH, MS, PhD, DACVP, DABT, National Toxicology Program, NIEHS, Research Triangle Park, NC*

One of the principal challenges of a toxicologic pathologist is to determine and differentiate a true adverse effect from an adaptive response. A number of factors can interfere with a clear, reasoned determination of adversity starting with the lack of consensus on the definition of adversity. In addition, the introduction of artifact, both in poor study design and in histopathology and other data sets can lead to an improper determination of adversity. This CE course will attempt to address these challenges in determining if a finding is adverse or not. The course begins with an overview and position statement from the STP committee on adverse versus adaptive effects and is followed by a discussion on how artifacts and spurious findings can complicate adversity determination. In addition, lectures with case examples will be provided from clinical pathology and anatomic pathology to determine adverse versus adaptive effects. The course will close with a regulatory perspective on interpreting adverse versus adaptive effects. This CE course is designed to provide practical knowledge with numerous relevant case examples in toxicologic pathology and would be useful to the practicing toxicologic pathologist.

1:30 PM–2:10 PM	<b>What Is an Adverse Effect in Toxicologic Pathology?</b> <i>Roy L. Kerlin, BVSc, PhD, DACVP, Pfizer, Inc., Groton, CT</i>
2:10 PM–2:50 PM	<b>Adverse or Adaptive? No, It Is an Artifact</b> <i>Peter Mann, DVM, PhD, EPL Northwest, Seattle, WA</i>
2:50 PM–3:20 PM	<b>Break</b>
3:20 PM–4:00 PM	<b>Clinical Pathology Parameters and Establishing a NOAEL</b> <i>Nancy Everds, DVM, DACVP, Amgen, Inc., South San Francisco, CA</i>
4:00 PM–4:40 PM	<b>Adaptive, Non-Adverse, and Adverse Responses in Nonclinical Studies</b> <i>Alok K. Sharma, BVSc, MVSc, MS, PhD, DACVP, DABT, Covance Laboratories, Inc., Madison, WI</i>
4:40 PM–5:20 PM	<b>Regulatory Perspective on Adverse versus Adaptive Responses in Toxicologic Pathology</b> <i>Peyton Myers, PhD, US FDA, Silver Spring, MD</i>
5:20 PM–5:30 PM	<b>Questions and Discussion</b>
5:30 PM–7:00 PM	<b>Welcome Reception</b> Grand Hall C

**Continuing Education Course and Scientific Session Credits**

**AAVSB RACE Provider #56**

The CE Courses are approved by the AAVSB RACE to offer a total of 3.50 CE Credits per course (3.50 max) being available to any one veterinarian: and/or 3.50 Veterinary Technician CE Credits (3.50 max). This RACE approval is for the subject matter category(s) of: Category One: Scientific using the delivery method(s) of: Seminar/Lecture. The Scientific Sessions are approved by the AAVSB RACE to offer a total of 20.00 CE Credits (20.00 max) being available to any one veterinarian: and/or 20.00 Veterinary Technician CE Credits (20.00 max). This RACE approval is for the subject matter category(s) of: Category One: Scientific using the delivery method(s) of: Seminar/Lecture. These approvals are valid in jurisdictions which recognize AAVSB RACE; however, participants are responsible for ascertaining each board's CE requirements. Certificates of attendance will be provided at the conclusion each CE Course and also at the end of the final Scientific Session. Please contact the AAVSB RACE program if you have any comments/concerns regarding this program's validity or relevancy to the veterinary profession.

**Monday, June 27**

8:00 AM–8:10 AM	<b>Symposium Welcome</b> Grand Hall A
8:10 AM–9:00 AM	<b>Keynote Address: Cornerstones of Toxicology</b> <i>A. Wallace Hayes, PhD, DABT, ATS, FIBiol, FACFE, ERT, Harvard School of Public Health, Boston, MA and Michigan State University Institute for Integrative Toxicology, East Lansing, MI</i> Grand Hall A

**Session 1**

9:00 AM–12:00 Noon	<b>Real World Toxicology Outcomes: Impact of Species and Strain Selection on Drug Development Programs</b> <i>Co-Chairs: Diane Gunson, BVSc, PhD, DACVP, Novartis Pharmaceuticals Corporation, East Hanover, NJ; and Emily Meseck, DVM, DACVP, DABT, Novartis Pharmaceuticals Corporation, East Hanover, NJ</i>
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Selection of a rodent strain and non-rodent species for pharmacologic and toxicity testing has far ranging implications for drug development programs. Variation in toxicologic responses due to species or strain selection in drug safety programs will be explored through three detailed case studies and a comparison of neoplastic findings in toxicology studies between two common outbred rat strains. The impact of species and strain selection on variation in biologic and toxicologic responses and the impact of that variation on drug development programs, including program outcomes and mitigation strategies, will be discussed in the context of the case studies.

9:00 AM–9:10 AM	<p><b>Introduction</b>  <i>Diane Gunson, BVSc, PhD, DACVP, Novartis Pharmaceuticals Corporation, East Hanover, NJ</i></p>
9:10 AM–9:55 AM	<p><b>Differences in Types and Incidence of Neoplasms in Wistar Han and Sprague-Dawley Rats</b>  <i>Klaus Weber, DVM, MSBiol, PhD, Anapath GmbH, Oberbuchsitzen, Switzerland</i></p>
9:55 AM–10:25 AM	<p><b>Break (Sponsored by Covance Laboratories, Inc.)</b>  <b>Grand Hall C</b></p>
10:25 AM–11:00 AM	<p><b>Differences in Sensitivity between Cynomolgus Monkeys of Mauritian or Asian Origin</b>  <i>Peter K. Hoffmann, MD, PhD, Novartis Pharmaceuticals Corporation, East Hanover, NJ</i></p>
11:00 AM–11:20 AM	<p><b>Examples of the Impact of Species and Strain on Immunotoxicology Assessment</b>  <i>Ellen W. Evans, DVM, PhD, DACVP, Pfizer, Inc., Groton, CT</i></p>
11:20 AM–12:00 Noon	<p><b>Copovidone-Related Cutaneous Response in the Dog and Management of Pseudoallergic Responses in Beagle Dogs</b>  <i>John E. Sagartz, DVM, PhD, DACVP, Seventh Wave Laboratories, Maryland Heights, MO; and Sherry J. Morgan, DVM, PhD, DACVP, DABT, DABVT, AbbVie, Inc., North Chicago, IL</i></p>
12:00 Noon–1:30 PM	<p><b>Exhibitor-Sponsored Lunch</b>                  For Registered Scientific Attendees  <b>Grand Hall C</b></p>

## Career Development Lunchtime Series

Monday, June 27  
 12:30 PM–1:30 PM  
 Cortez Hill B  
 Sponsored by EPL, Inc.

### Interacting with Our MD Colleagues

**Presented by the STP Career Development and Outreach Committee**

*(Free Event, Registration Required)*

Chair: *Elizabeth Clark, DVM, The Ohio State University, Columbus, OH*

A panel of toxicologic pathologists, physicians, and/or MD pathologists will discuss ways to optimize the value of interactions between toxicologic pathology and medical colleagues during biopharmaceutical development. Topics for discussion may include the use and communication of preclinical data to inform clinical trial design, interpretation of clinical adverse events, regulatory submission, or tailoring therapies with tissue or fluid-based biomarkers. The goal of the panel discussion will be to create greater familiarity among STP members about the different roles of our physician colleagues and how we might improve our communication and collaboration with them to enhance biopharmaceutical development.

## Session 2

1:30 PM–5:00 PM

Grand Hall A

### Deciphering Sources of Variability in Clinical Pathology—It's Not Just About the Numbers

**Co-Chairs:** *Adam Aulbach, DVM, DACVP, MPI Research, Mattawan, MI; Anne Provencher, DVM, MSc, DACVP, DECVP, FIATP, Charles River Laboratories, Sherbrooke, Quebec, Canada; and Niraj Tripathi, BVSc, MVSc, PhD, DACVP, Covance Laboratories, Inc., Madison, WI*

This session will explore variability in Clinical Pathology data and its impact on the overall interpretation of the data and determination of toxicity and/or effect of experimental procedures. The presentations will discuss potential effects of many variables on clinical pathology parameters, from animal physiology to the collection process, specimen handling and analysis, from study design to the use of statistics, and how to manage those variables to ensure accurate interpretation of clinical pathology data in research and drug development. The first two presentations will focus on preanalytical and analytical variables that can influence clinical pathology data, and the third presentation will cover the influence of study design on clinical pathology results. After the break, a presentation on the use of statistics and reference intervals for data interpretation, as well as approach to qualifiers to describe a magnitude of changes in clinical pathology reports. The session will end with an interactive session of case reports/panel discussions where invited speakers will present cases/data on the different topics to generate discussion between the panel (speakers and co-chairs) and participants.

1:30 PM–1:35 PM

#### Introduction

*Adam Aulbach, DVM, DACVP, MPI Research, Mattawan, MI; Anne Provencher, DVM, MSc, DACVP, DECVP, FIATP, Charles River Laboratories, Sherbrooke, Quebec, Canada; and Niraj Tripathi, BVSc, MVSc, PhD, DACVP, Covance Laboratories, Inc., Madison, WI*

1:35 PM–2:10 PM

#### Preanalytical Considerations

*Nancy Everds, DVM, DACVP, Amgen, Inc., South San Francisco, CA*

2:10 PM–2:45 PM

#### Analytical Considerations

*A. Eric Schultze, DVM, PhD, DACVP, FIATP, Eli Lilly and Company, Indianapolis, IN*

2:45 PM–3:20 PM

#### Influence of Study Design Variables on Clinical Pathology Data

*Adam Aulbach, DVM, DACVP, MPI Research, Mattawan, MI; Anne Provencher, DVM, MSc, DACVP, DECVP, FIATP, Charles River Laboratories, Sherbrooke, Quebec, Canada; and Niraj Tripathi, BVSc, MVSc, PhD, DACVP, Covance Laboratories, Inc., Madison, WI*

3:20 PM–3:50 PM

**Break (Sponsored in part by Syngenta)**  
**Grand Hall C**

3:50 PM–4:25 PM

#### Statistics/Reference Intervals/Magnitudes and Qualifiers

*Robert Hall, DVM, PhD, DACVP, Covance Laboratories, Inc., Madison, WI*

4:25 PM–5:00 PM

Panel Discussion

**Tuesday, June 28**

**Session 3**

8:00 AM–12:00 Noon

Grand Hall A

**Influence of Experimental Design and Environmental Conditions**

*Co-Chairs: Theresa Boulineau, DVM, MS, DACVP, Novartis Institutes for Biomedical Research, East Hanover, NJ; and Sherry J. Morgan, DVM, PhD, DACVP, DABT, DABVT, AbbVie, Inc., North Chicago, IL*

Careful planning of studies is paramount to optimizing the probability of a successful study—one in which the results can be clearly interpreted and decisions can be made. Understanding the potential ramifications of experimental design on study interpretation is one of the major facets of study planning. Session 3 will cover some of the aspects of experimental design and potential associated environmental conditions that may affect the outcome of toxicology studies. The first two presentations will provide specific examples of how selection of species and strains (Cynomolgus monkey or rodents) can affect clinical or anatomic pathology results and interpretation. This will be followed by an in-depth discussion of the potential effect of vehicles/formulations on general toxicology studies (both clinical and anatomic pathology) as well as specific considerations for developmental/reproductive toxicology studies. An additional presentation will cover facets of study design (other than vehicles/formulations) on the outcome of developmental/reproductive toxicology studies. The session will conclude with a presentation on how bioinformatics may be utilized to optimize study design and interpretation.

8:00 AM–8:10 AM

**Introduction**

*Theresa Boulineau, DVM, MS, DACVP, Novartis Institutes for Biomedical Research, East Hanover, NJ; and Sherry J. Morgan, DVM, PhD, DACVP, DABT, DABVT, AbbVie, Inc., North Chicago, IL*

8:10 AM–8:45 AM

**Species/Strain Differences and How They Affect Study Designs and Outcomes—Anatomic Pathology**

*Karyn Colman, BVetMed, MRCVS, Novartis Institutes for Biomedical Research, East Hanover, NJ*

8:45 AM–9:20 AM

**Species/Strain Differences and How They Affect Study Designs and Outcomes—Clinical Pathology**

*Kirstin Barnhart, DVM, PhD, DACVP, AbbVie, Inc., North Chicago, IL*

9:20 AM–10:00 AM

**Break (Sponsored in Part by Eli Lilly and Company)**

Grand Hall C

10:00 AM–10:40 AM

**Multi-Functional Approach to the Topic of Vehicles/Formulations and Their Effect on Study Outcomes**

*Brian Enright, MS, PhD, DABT, AbbVie, Inc., North Chicago, IL; Katharine M. Whitney, DVM, PhD, DACVP, AbbVie, Inc., North Chicago, IL; and Michael Logan, DVM, PhD, DACVP, AbbVie, Inc., North Chicago, IL*

10:40 AM–11:20 AM

**Influence of Study Design in Developmental and Reproductive Toxicology Studies on Study Outcomes**

*Paul M.D. Foster, PhD, ATS, National Toxicology Program, NIEHS, Research Triangle Park, NC*

11:20 AM–12:00 Noon

**Modern Data Analysis—Bioinformatics: How It Can Be Used in Adaptive Study Design and Data Interpretation**

*Elizabeth V. Skuba, DVM, MVSc, DACVP, Novartis Institutes for BioMedical Research, East Hanover, NJ*

Afternoon

Free Time

**Wednesday, June 29**

**Session 4A**

8:00 AM–12:00 Noon

Grand Hall A

**Influence of Epigenetics, Genetics, and Immunology**

*Co-Chairs: Robert Johnson, DVM, PhD, Novartis, East Hanover, NJ; and Michael Leach, DVM, PhD, Pfizer, Inc., Andover, MA*

In nonclinical studies, variability in responses often occurs both within studies (inter-animal variability), as well as between studies using the same species. Potential causes of this variability include genetic and epigenetic variants. This is especially true for studies with nonhuman primates, which have genetic variability similar to that observed in the human population. However, examination of the role of genetics and epigenetics in variability in nonclinical studies has generally been limited. The objective of this session is to provide attendees with a basic understanding of both genetics and epigenetics, and the potential impact that genetic and epigenetic variants can have in nonclinical studies. In this session, a population analysis of cynomolgus monkey genetic variability, with a comparison to the human exome, will be presented, as well as case studies evaluating the functional impact of identified variants, and potential variants associated with toxic phenotypes such as drug-induced fulminant liver failure. This will provide the roadmap for a general strategy of assessing the impact of genetic variation of different phenotypes. This approach overall introduces a paradigm shift in using genetic characterization of species used in toxicity studies to understand the genetic basis of drug-associated toxicity signals. Although rodents used in toxicity studies are generally inbred and genetically identical, or outbred with limited genetic diversity, a diversity outbred (DO) population of mice was recently established with the aim of improving the prediction of human safety risk. As an example, DO mice have been used to model idiosyncratic liver injury caused by pharmaceutical drugs and herbal supplements. DO mice can also be used for whole genome association analyses to identify translational pharmacogenetics risk factors for toxicity, and examples of this will be presented. In addition, the utility of integrated genome-wide epigenomic and transcriptomic profiling of tissues from animal models will be discussed with particular emphasis on the mechanistic basis for species-specific differences in non-genotoxic hepatocarcinogenesis and implications for human cancer risk assessment. The session will conclude with a presentation discussing the role of epigenetic regulation of endothelial cell (EC)

function. Endothelial dysfunction is directly or indirectly involved in >70% of all cases of human death, most notably due to their central role in cardiovascular disease and tumors. Recent advances in whole genome analyses have shed unexpected light into the contribution of epigenetic modifications as regulator of EC phenotype and function. The presentation will prototypically present the role of epigenetic EC changes during adolescent vessel maturation.

8:00 AM–8:05 AM **Introduction**  
*Robert Johnson, DVM, PhD, Novartis, East Hanover, NJ; and Michael Leach, DVM, PhD, Pfizer, Inc., Andover, MA*

8:05 AM–8:40 AM **Genetic Variation in Non-Human Primates and Impact for Toxicology Programs**  
*Jonathan Moggs, PhD, Novartis Institutes for Biomedical Research, Basel, Switzerland*

8:40 AM–9:15 AM **Genetics: A Factor to Consider in Drug Safety Assessment Studies Using Cynomolgus Monkeys**  
*Karissa Adkins, PhD, Pfizer, Inc., Groton, CT*

9:15 AM–9:50 AM **Low Frequency Clinical Adverse Drug Reactions Can Be Predicted and Studied by Using Genetically Diverse Mouse Populations**  
*Alison Harrill, PhD, University of Arkansas for Medical Sciences, Little Rock, AR*

9:50 AM–10:05 AM **Student Presentation: In Vivo Loss of TGF-beta Receptors Type-1 and -2 in Cdh5-Lineage Cells Alters Acute Polymeric Graft Remodeling**  
*Elizabeth Clark, DVM, The Ohio State University, Columbus, OH*

10:05 AM–10:40 AM **Break**  
**Grand Hall C**

10:40 AM–11:15 AM **Epigenetics in Toxicology**  
*Jonathan Moggs, PhD, Novartis Institutes for Biomedical Research, Basel, Switzerland*

11:15 AM–12:00 Noon **Epigenetics and Angiogenesis**  
*Hellmut Augustin, ProfDrMedVet, PhD, Deutsches Krebsforschungszentrum (DKNZ), Heidelberg, Germany*

## Postnatal Organ Development As a Complicating Factor in Juvenile Toxicity Studies

*Sponsored by IATP and STP*

**12:00 Noon–1:30 PM**

**Cortez Hill B**

**Co-Chairs:** *George A. Parker, DVM, PhD, DACVP, DABT, WIL Research, Hillsborough, NC; and Catherine Picut, VMD, JD, DABT, DACVP, WIL Research, Hillsborough, NC*

In this practical approach to evaluating juvenile toxicity studies in rodent models, speakers will present a spectrum of histological changes not commonly seen in conventional toxicity studies.

## Session 4B

**1:30 PM–5:00 PM**

**Grand Hall A**

### Influence of Epigenetics, Genetics, and Immunology

**Co-Chairs:** *Cory Brayton, DVM, Johns Hopkins University School of Medicine, Baltimore, MD; and Paul W. Snyder, DVM, PhD, EPL, Inc., West Lafayette, IN*

Between and within species used to model human conditions, variation in responses to experimental interventions has often confounded results and made interpretation to humans difficult. The limitations to models include confounding, disparate, or otherwise problematic research outcomes; and for poor reproducibility and poor predictivity of translational studies. Examples of even a few immune relevant genotypes predict divergent immune and disease phenotypes, and illustrate that model animals must be assessed critically for their suitability for a particular disease. Accurate and broad-based genotype and phenotype data should be applied to model selection in an attempt to explain unexpected or disparate findings, or poor reproducibility. In the final talk of this session, the presenter will highlight some interactions with environmental factors, using examples of mouse strain-related differences in allergy induced responses to common environmental or novel allergens, and the implications for public and precision health. Mice and macaque are emphasized in this session.

1:30 PM–1:35 PM

#### Introduction

*Cory Brayton, DVM, Johns Hopkins University School of Medicine, Baltimore, MD; and Paul W. Snyder, DVM, PhD, EPL, Inc., West Lafayette, IN*

1:35 PM–2:15 PM

#### Translating Rodent Models—Immune Variation and Efficacy Testing

*Rani Sellers, DVM, PhD, DACVP, Pfizer, Inc., Pearl River, NY*

2:15 PM–2:55 PM

#### Immunological Variation, Including Inflammatory SNPs and Influenza Studies

*Gary J. Bursleson, PhD, Bursleson Research Technologies, Inc., Morrisville, NC*

2:55 PM–3:25 PM

#### Break

**Grand Hall Foyer**

3:25 PM–3:40 PM

#### Student Presentation: Morphine Treatment Potentiates *Citrobacter rodentium* Virulence, Systemic Dissemination, and Exacerbates Gut Dysbiosis in Mice

*Fuyuan Wang, DVM, MS, PhD, University of Minnesota, St. Paul, MN*

3:40 PM–4:20 PM

#### Immunologic Variation Attributable to MHC Differences in Macaques

*Nicholas J. Maness, PhD, Tulane National Primate Research Center, Covington, LA*

4:20 PM–5:00 PM **Strain- and Environment-Related Factors in Murine Models of Allergic Airway Disease**  
*Jack R. Harkema, DVM, PhD, DACVP, Michigan State University, East Lansing, MI*

5:30 PM–5:50 PM **Awards Ceremony**  
*Grand Hall A*

5:50 PM–6:30 PM **Annual Business Meeting**  
*Grand Hall A*

7:00 PM–9:00 PM **President's Reception**  
*Grand Hall C*

**Thursday, June 30**

**Session 5**

8:00 AM–12:00 Noon

*Grand Hall A*

**Influence of Age, Hormones, and the Microbiome**

*Co-Chairs: Dinesh J. Stanislaus, PhD, GlaxoSmithKline, King of Prussia, PA; and Justin D. Vidal, DVM, PhD, Vet Path Services, Inc., Blue Bell, PA*

The objective of this session is to discuss and elaborate on how age, hormones, and microbiome can influence toxicologic response in animals. The first presentation will provide an overview of variability in toxicology testing and discuss how underlying hormonal differences between sexes affect drug metabolism and resulting toxicologic responses. The session will next focus on the new emerging field of the microbiome and present current knowledge on how the microbiome acts as a gatekeeper to control access to chemicals and how that affects toxicologic responses. The third presentation will explore the impact of age and timing of dosing on toxicologic response. The last two presentations will be changing the direction of the discussion to more practical applications and will go into detail on how age-related changes affect the interpretation of male and female reproductive tract pathology.

8:00 AM–8:05 AM **Introduction**  
*Dinesh J. Stanislaus, PhD, GlaxoSmithKline, King of Prussia, PA; and Justin D. Vidal, DVM, PhD, Vet Path Services, Inc., Blue Bell, PA*

8:05 AM–8:45 AM **Sex Differences in Human and Animal Toxicology**  
*Michael Gochfeld, MD, PhD, Rutgers University, Piscataway, NJ*

8:45 AM–9:25 AM **New Models for Toxicology: The Microbiome**  
*Ellen Kovner Silbergeld, PhD, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD*

9:25 AM–10:05 AM **Timing of Exposure and Windows of Sensitivity in Toxicity Testing**  
*Paul M.D. Foster, PhD, ATS, National Toxicology Program, NIEHS, Research Triangle Park, NC*

10:05 AM–10:40 AM **Break**  
*Grand Hall Foyer*

10:40 AM–11:20 AM **Impact of Age on the Male Reproductive System from the Pathologist's Perspective**  
*Amera Remick, DVM, DACVP, DABT, WIL Research, Hillsborough, NC*

11:20 AM–12:00 Noon **Impact of Age on the Female Reproductive System from the Pathologist's Perspective**  
*Justin D. Vidal, DVM, PhD, Vet Path Services, Inc., Blue Bell, PA*

12:00 Noon **Meeting Adjourned**



## Society of Toxicologic Pathology

### Modular Education Course: Toxicologic Pathology of the Hepatobiliary System

**October 23–26, 2016**  
Embassy Suites Raleigh-Durham  
Raleigh, North Carolina

**Challenging Real-World Hepatobiliary Pathology Examples from Multiple Preclinical Species**

**Review of Inhand Hepatobiliary Nomenclature**

**Clinical Pathology and Interpretation of Current and Novel Liver Injury Biomarkers**

**Xenobiotic Induced Liver Carcinogenesis**

**Advances in Animal Models Used in Hepatic Toxicity Investigation and Their Translational Significance**

**Hepatotoxicity Comprehensive Risk Assessment**

**Discussion of Liver Histopathology Examples Submitted in Advance by Participants**

**Microscopy Sessions on Non-Neoplastic and Neoplastic Hepatobiliary Pathology Examples**

**Emerging Challenges from the Clinical Setting, Including Comorbidity (Nash and Other Forms of Hepatitis), Patient Idiosyncrasy (Including Immune Response), and Other Co-Factors**



*On behalf of STP Education Committee*  
Course Chair: Sunish Mohanan (Eli Lilly and Company);  
Course Co-Chairs: John Cullen (North Carolina State University); and Russell Cattley (Auburn University)

Please visit [www.toxpathath.org](http://www.toxpathath.org) to register and for more information.

Topics subject to change.

## Poster Times and Poster Setup

### Poster Setup

Sunday, June 26..... 8:00 AM–3:00 PM  
 Your poster must be set up by 3:00 PM on Sunday, June 26, 2016.

### Poster Presentation Times

**(Please plan to attend your posters during the following times)**

Sunday, June 26 (Welcome Reception)..... 6:00 PM–6:30 PM  
 Monday, June 27..... 9:55 AM–10:25 AM and 3:20 PM–3:50 PM  
 Tuesday, June 28..... 9:20 AM–10:00 AM  
 Wednesday, June 29..... 10:05 AM–10:40 AM

### Poster Teardown

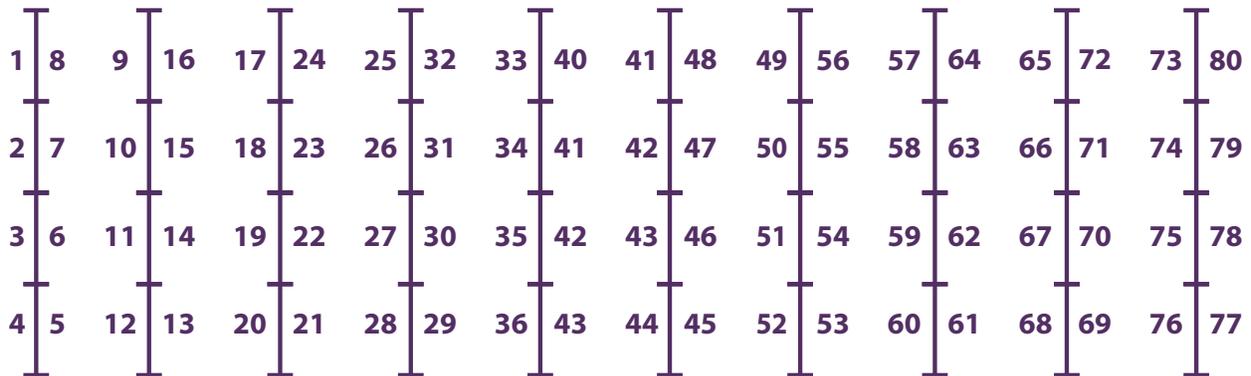
Wednesday, June 29..... 11:30 AM–1:00 PM  
 If your poster is not removed before 1:00 pm on Wednesday, June 29, it will be removed and placed near the Registration Desk for pick up.

### Young Investigator Judging Times

Monday, June 27..... 7:15 AM–8:00 AM, 10:30 AM–11:00 AM, and 3:00 PM–3:35 PM  
 Tuesday, June 28..... 9:45 AM–10:20 AM

## Manchester Grand Hyatt—Exhibit Hall

### Poster Map



Exhibitor Map on page 30.

**Entrance**

## Poster Presentation Index

Annual Meeting materials can also be downloaded at [www.toxpath.org/am2016/materials.asp](http://www.toxpath.org/am2016/materials.asp).

STP members can access with their normal member login. Nonmember attendees should use the login sent via email.

### Poster Categories:

Young Investigator Candidates 1–18

Biomarkers 19–22

General Pathology/Toxicologic Pathology 23–40

New Technologies 41–50

Oncology/Carcinogenesis 51–57

Systemic/Organ-Specific Toxicologic Pathology 58–78

### 1 Usefulness of Optical Coherence Tomography to Detect Central Serous Chorioretinopathy in Monkeys

Hyun-Kyu Park<sup>1,2</sup>, Woori Jo<sup>1,2</sup>, Hyun-Ji Choi<sup>1,2</sup>, Bongcheol Kim<sup>1,2</sup>, Gilnam Lee<sup>3</sup>, Jeongbeob Seo<sup>3</sup>, Suk Young Cho<sup>4</sup>, Choung-Soo Kim<sup>1,2</sup>, Eun Kyung Choi<sup>1,2</sup>, Jung Jin Hwang<sup>2</sup>, Joo Yong Lee<sup>1,2</sup>, Young Hee Yoon<sup>1,2</sup>, Woo-Chan Son<sup>1,2</sup>, <sup>1</sup>University of Ulsan College of Medicine, Seoul, Republic of Korea, <sup>2</sup>Asan Medical Center, Seoul, Republic of Korea, <sup>3</sup>CHABIOMED Co. LTD, Seongnam, Republic of Korea, <sup>4</sup>WuXi App Tec Co. LTD, Shanghai, China

### 2 Evaluation of Nonalcoholic Fatty Liver Disease in C57BL/6J Mice by Using MRI and Histopathologic Analyses

Jae-Eun Ryu<sup>1</sup>, Woo-ri Jo<sup>1</sup>, Hyun-Ji Choi<sup>1</sup>, Sung-wong Jang<sup>1</sup>, Hyo-Ju Lee<sup>1</sup>, Dong-Cheul Woo<sup>1</sup>, Jeong Kon Kim<sup>1</sup>, Kyung Won Kim<sup>1</sup>, Eun Sil Yu<sup>1</sup>, Ji Hye Mun<sup>1</sup>, Woo-Chan Son<sup>1</sup>, <sup>1</sup>University of Ulsan College of Medicine, Seoul, Republic of Korea

### 3 Circulating Biomarkers Indicate Severe Mitochondrial Dysfunction During Drug-Induced Ischemic Hepatitis

James L. Weemhoff<sup>1</sup>, Benjamin L. Woolbright<sup>1</sup>, Mitchell R. McGill<sup>1</sup>, Steven C. Curry<sup>2</sup>, Daniel J. Antoine<sup>3</sup>, Hartmut Jaeschke<sup>1</sup>, <sup>1</sup>Department of Pharmacology, Toxicology, and Therapeutics, University of Kansas Medical Center, Kansas City, KS, US, <sup>2</sup>Department of Medical Toxicology, Banner Good Samaritan Medical Center, Department of Medicine, University of Arizona College of Medicine, Phoenix, AZ, US, <sup>3</sup>MRC Centre for Drug Safety Science, Department of Molecular and Clinical Pharmacology, Institute of Translational Medicine, University of Liverpool, Liverpool, UK

### 4 Chorioretinal Dysplasia in Sprague-Dawley Rats: Ophthalmologic and Histopathologic Characterization

Leah Stein<sup>1</sup>, Keith Nelson<sup>1,2</sup>, Joshua Bartoe<sup>1,2</sup>, Betsy Geddings<sup>2</sup>, <sup>1</sup>Michigan State University, East Lansing, MI, US, <sup>2</sup>MPI Research, Mattawan, MI, US

### 5 Morphine Treatment Potentiates *Citrobacter rodentium* Virulence, Systemic Dissemination and Exacerbates Gut Dysbiosis in Mice

Fuyuan Wang<sup>1</sup>, Jingjing Meng<sup>2</sup>, Sabita Roy<sup>2,3</sup>, <sup>1</sup>University of Minnesota, College of Veterinary Medicine, St. Paul, MN, US, <sup>2</sup>University of Minnesota, Medical School, Department of Surgery, Minneapolis, MN, US, <sup>3</sup>University of Minnesota, Medical School, Department of Pharmacology, Minneapolis, MN, US

### 6 A Preliminary Toxicity Study of *Curcuma longa* Extract for the Control of *Salmonella* Spp. in Pigs

Hong-Seok Lee<sup>1,2</sup>, Na-Yon Kim<sup>1,2</sup>, Myung-Chul Kim<sup>1,2</sup>, Yu-Ri Seo<sup>1</sup>, Hyung Tae Lee<sup>4</sup>, Dalmuri Han<sup>4</sup>, June Bong Lee<sup>4</sup>, Jang Won Yoon<sup>4</sup>, Yongbaek Kim<sup>1,3</sup>, <sup>1</sup>Laboratory of Clinical Pathology, College of Veterinary Medicine, Seoul National University, Seoul, Republic of Korea, <sup>2</sup>BK 21 PLUS Program for Creative Veterinary Science Research, College of Veterinary Medicine, Seoul National University, Seoul, Republic of Korea, <sup>3</sup>Research Institute for Veterinary Science, College of Veterinary Medicine, Seoul National University, Seoul, Republic of Korea, <sup>4</sup>College of Veterinary Medicine & Institute of Veterinary Science, Gangwon National University, Gangwon, Republic of Korea

### 7 Generation and Characterization of a Novel Mouse Model of Primary Biliary Cirrhosis

Sonika Patial<sup>1</sup>, Perry Blackshear<sup>1</sup>, <sup>1</sup>NIEHS, Research Triangle Park, NC, US

### 8 Immunopathologic Effects of Prednisolone and Cyclosporine A on FIV Replication and Persistence

Craig Miller<sup>1</sup>, Esther Musselman<sup>1</sup>, Jordan Powers<sup>1</sup>, Ryan Mackie<sup>1</sup>, Susan VandeWoude<sup>1</sup>, <sup>1</sup>Colorado State University, Fort Collins, CO, US

### 9 In Vivo Loss of TGF-beta Receptors Type-1 and -2 in Cdh5-Lineage Cells Alters Acute Polymeric Graft Remodeling

Elizabeth Clark<sup>1,2</sup>, Nathan Mahler<sup>1,2</sup>, Tai Yi<sup>2</sup>, George Tellides<sup>3</sup>, Christopher Breuer<sup>1,2</sup>, <sup>1</sup>The Ohio State University, Columbus, OH, US, <sup>2</sup>Nationwide Children's Hospital, Columbus, OH, US, <sup>3</sup>Yale University, New Haven, CT, US

### 10 Establishment of a Novel Chronic Hyperplastic Candidiasis Model with Carcinoma in Type 1 Diabetic Mice

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### 11 The Effect of HDACi (AR-42) on Canine Prostate Cancer Metastasis

Said Elshafae<sup>1</sup>, Nicole Kohart<sup>1</sup>, Lucas Altstadt<sup>1</sup>, Wessel Dirksen<sup>1</sup>, Thomas Rosol<sup>1</sup>, <sup>1</sup>Ohio State University, Columbus, OH, US

### 12 Evaluation of Hotspot Mutations in *Idh1*, *Idh2*, *Braf*, and *Egfr* Genes in Rat Glial Tumors

Miaofei Xu<sup>1</sup>, Hue-Hua Hong<sup>1</sup>, Ramesh Kovi<sup>1,2</sup>, Kyathanahalli Janardhan<sup>3</sup>, Susan Elmore<sup>1</sup>, Paul Foster<sup>1</sup>, John Bucher<sup>1</sup>, Robert Sills<sup>1</sup>, Arun Pandiri<sup>1</sup>, <sup>1</sup>Division of National Toxicology Program (DNTP), NIEHS, Research Triangle Park, NC, US, <sup>2</sup>Experimental Pathology Laboratories Inc., Research Triangle Park, NC, US, <sup>3</sup>Integrated Laboratory Systems, Research Triangle Park, NC, US

## 13 Expression of Immune Checkpoint Molecules in Mantle Cell Lymphoma

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## 14 Suppression of Ovarian Cancer Growth and Metastasis with HO-3867, a STAT3 Inhibitor, in Ex Vivo Slice Culture of Human Tumors and Orthotopic Tumor Mouse Models

Shan Naidu<sup>1,2</sup>, Uksha Saini<sup>2</sup>, Adam ElNaggar<sup>2</sup>, Hemant Bid<sup>2</sup>, Ross Wanner<sup>2</sup>, Emily Sudhakar<sup>2</sup>, Adrian Suarez<sup>2</sup>, Jeff Hays<sup>2</sup>, Peter Houghton<sup>2</sup>, Nobuko Wakamatsu<sup>1</sup>, David Cohn<sup>2</sup>, Karuppaiyah Selvendiran<sup>2</sup>, <sup>1</sup>Louisiana State University, Baton Rouge, LA, US, <sup>2</sup>The Ohio State University, Columbus, OH, US

## 15 Effect of Histone Deacetylase Inhibitor (AR-42) on Feline Mammary Cancer In Vivo and In Vitro

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## 16 Discovery of Ethyl Urea Derivatives as Inhibitors of Human Islet Amyloid Polypeptide Fibrillization and Cytotoxicity

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## 17 Strain-Specific Sensitivity and Resistance to Carbon Nanotube Lung Exposures Among Common Inbred Strains of Mice

Evan Frank<sup>1</sup>, Vinicius Carreira<sup>1</sup>, Kumar Shanmukhappa<sup>2</sup>, Mario Medvedovic<sup>1</sup>, Dan Prows<sup>2</sup>, Jagjit Yadav<sup>1</sup>, <sup>1</sup>University of Cincinnati, Cincinnati, OH, US, <sup>2</sup>Cincinnati Children's Hospital Medical Center, Cincinnati, OH, US

## 18 Differential Receptor Tyrosine Kinase Phosphorylation in Uterine Tissue of Rats following Developmental Exposure to Tetrabromobisphenol A

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## 19 Biotinylated Mouse Anti-Human HER2 Monoclonal Antibody in Normal Fresh Human and Cynomolgus Monkey Tissues

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## 20 Induction of Inflammatory SMAD7 Expression in a Model of Anti-CD40 Antibody-Induced Acute Innate Colitis in Mice

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## 21 Effect of Time and Storage Conditions on Prothrombin Time, Activated Partial Thromboplastin Time, and Fibrinogen Concentration in Rat Sodium Citrate Plasma Samples

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## 22 Chaperone-Mediated Autophagy in Renal Tubules after Treatment with a PEG-Linked Protein: In Vitro and In Vivo Tools for Early Screening of Reversible Kidney Tubular Epithelial Cell Toxicity

James McDuffie<sup>1</sup>, Steven Lee<sup>1</sup>, Jing Ying Ma<sup>1</sup>, Sinae Lee<sup>1</sup>, Justin Kanerva<sup>1</sup>, Yafei Chen<sup>1</sup>, Sandra Snook<sup>1</sup>, Freddy Schoetens<sup>1</sup>, <sup>1</sup>Janssen Research & Development, LLC, San Diego, CA, US

## 23 Spontaneous Findings in the Eyes of Mauritian Cynomolgus Monkeys (*Macaca fascicularis*)

Jochen Woicke<sup>1</sup>, Solomon Haile<sup>2</sup>, Jagannatha V. Mysore<sup>1</sup>, W. Michael Peden<sup>1</sup>, Typhaine Lejeune<sup>2</sup>, Thomas A. Brodie<sup>1</sup>, Thomas P. Sanderson<sup>1</sup>, <sup>1</sup>Bristol-Myers Squibb Research and Development, Drug Safety Evaluation, Princeton, NJ, US, <sup>2</sup>Charles River Laboratories, Preclinical Services, Pathology Division, Senneville, Quebec, Canada

## 24 The Cynomolgus Macaque Model of Pneumonic Tularemia

Lynda Lanning<sup>1</sup>, Patrick Sanz<sup>1</sup>, Larry Wolfrain<sup>1</sup>, Christopher Houchens<sup>2</sup>, Kristian Omland<sup>3</sup>, Mark Williams<sup>1</sup>, Judith Hewitt<sup>1</sup>, Tina Guina<sup>1</sup>, <sup>1</sup>NIAID/NIH/HHS, Bethesda, MD, US, <sup>2</sup>BARDA, Washington, DC, US, <sup>3</sup>Mergus Analytics, Jericho, VT, US

## 25 Acute Alloxan Toxicity Initially Causes Degeneration of Thick Ascending Limbs of Henle without Involving GLUT2

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## 26 Comparison of Coumarin-Induced Acute and Chronic Hepatotoxicity of Rat

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## 27 Procedure Related Findings in Rats with Application of Restraints around the Torso and Neck

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**28 Reflux-Related Otitis Media and Meningitis in Rats after Gavage Dosing**

Hetty van den Brink-Knol<sup>1</sup>, Nils Krueger<sup>2</sup>, Klaus Weber<sup>3</sup>, <sup>1</sup>WIL Research Europe B.V., 's-Hertogenbosch, Netherlands, <sup>2</sup>Evonik Resource Efficiency GmbH, Hanau-Wolfgang, Germany, <sup>3</sup>AnaPath GmbH, Liestal, Switzerland

**29 Non-Neoplastic Ocular Histologic Background Findings in Sprague-Dawley Rats at MPI Research**

Leah Stein<sup>1</sup>, Keith Nelson<sup>1,2</sup>, <sup>1</sup>Michigan State University, East Lansing, MI, US, <sup>2</sup>MPI Research, Mattawan, MI, US

**30 Tail Cuff-Infused Nude Mice: Comparison of Continuous versus Intermittent Tethering with the Pinport-in-Tail Cuff System, Histopathological Parameters.**

Elke Hartmann<sup>1</sup>, Uta Wimitzer<sup>1</sup>, Hans van Wijk<sup>2</sup>, <sup>1</sup>BAYER Pharma AG, Wuppertal, Germany, <sup>2</sup>Covance Laboratories, Harrogate, UK

**31 In Vivo Microdialysis of the Rodent Brain: Challenges to Refine Stereotaxic Coordinates and Tissue Reaction**

Karen Bodié<sup>1</sup>, Kerstin Buck<sup>1</sup>, <sup>1</sup>Abbvie Deutschland GmbH & Co. KG, Ludwigshafen, Germany

**32 Trauma As a Cause for Hepatopathy in Newborn Göttingen Minipigs: A Procedure-Related Finding Complicating Interpretation of Toxicity Studies**

Yuval Ramot<sup>1</sup>, Klaus Weber<sup>2</sup>, Beatriz Moreno Lobato<sup>3</sup>, Francisco Miguel Sánchez Margallo<sup>3</sup>, José Francisco Guillén Caro<sup>3</sup>, Luis Dávila Gómez<sup>3</sup>, Roni Shabat<sup>4</sup>, Abraham Nyska<sup>5,6</sup>, <sup>1</sup>Hadassah Hebrew University Medical Center, Jerusalem, Israel, <sup>2</sup>AnaPath GmbH, Oberbuchsitzen, Switzerland, <sup>3</sup>Centro de Cirugía de Mínima Invasión (CCMI), Cáceres, Spain, <sup>4</sup>CCMI Israel Ltd, Nazareth, Israel, <sup>5</sup>Sackler School of Medicine, Tel Aviv University, Tel Aviv, Israel, <sup>6</sup>Consultant in Toxicologic Pathology, Timrat, Israel

**33 Histopathology in Large Scale Mouse Phenotype Screen Reveals Novel Disease Mechanisms and Models: Potential Application in Drug Discovery and Safety Assessment**

Hibret Adissu<sup>1,2</sup>, Susan Newbigging<sup>2</sup>, Lily Morikawa<sup>2</sup>, Jacqueline White<sup>3</sup>, Colin McKerlie<sup>2</sup>, <sup>1</sup>Covance Laboratories Inc, Greenfield, IN, US, <sup>2</sup>The Centre for Phenogenomics, Toronto, Ontario, Canada, <sup>3</sup>The Wellcome Trust Sanger Institute, Hinxton, UK

**34 The Minipig: An Alternative Animal Model for the Evaluation of Anti-Neoplastic Drugs**

Rosa Anna Manno<sup>1</sup>, Andrea Grassetto<sup>1</sup>, Raffaella Capobianco<sup>1</sup>, Germano Oberto<sup>1</sup>, <sup>1</sup>Research Toxicology Centre, Pomezia, Rome, Italy

**35 Genotoxicity of the Flavoring Agent, Perillaldehyde**

Shim-mo Hayashi<sup>1,2</sup>, Cheryl Hobbs<sup>3</sup>, Robert Maronpot<sup>4</sup>, Carol Beevers<sup>5</sup>, Mel Lloyd<sup>5</sup>, Rachael Bowen<sup>5</sup>, Lucinda Lillford<sup>5</sup>, Sean Taylor<sup>6</sup>, <sup>1</sup>Japan Flavor & Fragrance Materials Association, Tokyo, Japan, <sup>2</sup>San-Ei Gen, F.f.I., Inc., Osaka, Japan, <sup>3</sup>Integrated Laboratory Systems, Inc., Durham, NC, US, <sup>4</sup>Maronpot Consulting LLC, Raleigh, NC, US, <sup>5</sup>Covance Laboratories Ltd, Harrogate, UK, <sup>6</sup>International Organization of the Flavor Industry, Washington, DC, US

**36 Percentage of In Vitro Hemolysis in Laboratory Species**

Josely Figueiredo<sup>1</sup>, Carol Wally<sup>1</sup>, Bradley Buczynski<sup>1</sup>, Bruce Saltzgeber<sup>1</sup>, Donald Stump<sup>1</sup>, <sup>1</sup>WIL Research, Ashland, OH, US

**37 Pathological Review of Repeated Dose Dermal Toxicity 28-Day Studies of Nanomaterials (Silver, MWCNT, TiO<sub>2</sub>) in Sprague-Dawley Rats**

Hye Jin Kim<sup>1</sup>, Kyu Sup An<sup>1</sup>, Jae Hyuck Sung<sup>1</sup>, Hyeon Yeol Ryu<sup>1</sup>, Byung Gil Choi<sup>1</sup>, Jin Kyu Lee<sup>1</sup>, Kyung Seuk Song<sup>1</sup>, <sup>1</sup>Korea Conformity Laboratories (KCL), Incheon, Republic of Korea

**38 Intracytoplasmic Inclusions Containing Icosahedral Viral Particles in Renal Papillary Epithelium in Beagle Dogs**

Mohamoud Abdi<sup>1</sup>, <sup>1</sup>GlaxoSmithKline, Ware, Hertfordshire, UK

**39 Human Tissue and Veterinary Pathologists: What Are Our Boundaries in Drug Development?**

Richard Haworth<sup>1</sup>, David Krull<sup>2</sup>, Gail Pearce<sup>1</sup>, Cindy Fishman<sup>2</sup>, <sup>1</sup>GlaxoSmithKline, Ware, UK, <sup>2</sup>GlaxoSmithKline, Philadelphia, PA, US

**40 Oral Exposure to 4,6-Dinitroamino-1,3,5-triazine-2(1h)-one (DNAM) Is Associated with Intestinal and Renal Lesions in Male But Not Female Sprague-Dawley Rats**

Erica Carroll<sup>1</sup>, Lee Crouse<sup>1</sup>, <sup>1</sup>Army Public Health Center (Provisional), Aberdeen Proving Ground, MD, US

**41 Localization of Phospholipidosis on Light Microscopy: Use of Paraphenylenediamine Staining on Semi-Thin Tissue Sections**

Norimitsu Shirai<sup>1</sup>, Frank Geoly<sup>1</sup>, Walter Bobrowski<sup>1</sup>, Carlin Okerberg<sup>1</sup>, <sup>1</sup>Pfizer Inc., Groton, Connecticut, US

**42 The Use of In Vivo and Ex Vivo Compact Magnetic Resonance Imaging (MRI) for the Assessment of Tumorigenicity following Intrathecal Transplantation of Human Embryonic Stem Cells (hESC) in NOD-SCID Mice**

Yael Schifffenbauer<sup>3</sup>, Netanel Amouyal<sup>2</sup>, Nati Ezov<sup>2</sup>, Michal Steiner<sup>2</sup>, Michal Izrael<sup>4</sup>, Neta Lavon<sup>4</sup>, Arik Hasson<sup>4</sup>, Michele Revel<sup>4</sup>, Abraham Nyska<sup>1,5</sup>, <sup>1</sup>Tel Aviv University, Tel Aviv, Israel, <sup>2</sup>Envigo CRS, Ness Ziona, Israel, <sup>3</sup>Aspect Imaging, Shoham, Israel, <sup>4</sup>Kadimastem, Ness Ziona, Israel, <sup>5</sup>Consultant in Toxicologic Pathology, Timrat, Israel

**43 Antibody-Enhanced Intracellular Killing of Leishmania amazonensis Can Be Achieved by the Activation of Macrophages with Soluble Immune Complexes and Novel Recombinant Fc Constructs**

Marie Bockenstedt<sup>1</sup>, Adam Barb<sup>2</sup>, Brett Sponseller<sup>2</sup>, Doug Jones<sup>2</sup>, <sup>1</sup>Covance Laboratories, Madison, WI, US, <sup>2</sup>Iowa State University, Ames, IA, US

## 44 A Simple Method for Formalin Fixation of Lungs in Toxicological Pathology Studies

Ji-Ye Yin<sup>1</sup>, Wen-Sheng Qu<sup>1</sup>, He-Mei Wang<sup>1</sup>, Yan-Sheng Dong<sup>1</sup>, Quan-Jun Wang<sup>1</sup>, <sup>1</sup>Beijing Institute of Pharmacology and Toxicology, Beijing, China

## 45 Corneal Wound Healing Drug Effects in an Ex Vivo Human Front of the Eye Model in Comparison to Rabbit

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## 46 Evaluating Innate Immune Cell Immunotoxicity of a Novel Therapeutic Delivery System: Assessing Immunotoxicity of Extracellular Vesicles in Human Monocytic Cell Lines

Lucia Rosas<sup>2</sup>, Ola Elgamal<sup>3</sup>, Xiaokui Mo<sup>2</sup>, Mitch Phelps<sup>2</sup>, Thomas Schmittgen<sup>3</sup>, Tracey Papenfuss<sup>1</sup>, <sup>1</sup>WIL Research Laboratories, Ashland, OH, US, <sup>2</sup>The Ohio State University, Columbus, OH, US, <sup>3</sup>University of Florida, Gainesville, FL, US

## 47 Secure File Transfer Protocol (sFTP) for Electronic Exchange of Digital Pathology Data between Contract Research Organizations and Novartis Preclinical Safety

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## 48 ESTP Digital Imaging Survey: Preliminary Results

Erio Barale-thomas<sup>1</sup>, Jan Klapwijk<sup>2</sup>, <sup>1</sup>Johnson and Johnson, Beersen, Belgium, <sup>2</sup>GlaxoSmithKline, Ware, UK

## 49 Using Morphometric Features Extracted by Image Analysis to Identify T-Lymphocytes in IHC-Stained Tissues Independent of CD3 Staining

Famke Aeffner<sup>1</sup>, Nathan T. Martin<sup>1</sup>, Joshua Black<sup>1</sup>, Logan Cerkovnik<sup>1</sup>, Luke Pratte<sup>1</sup>, Staci J. Kearney<sup>1</sup>, Anthony J. Milici<sup>1</sup>, Joseph Krueger<sup>1</sup>, <sup>1</sup>Flagship Biosciences, Westminster, CO, US

## 50 Utilizing Digital Image Analysis to Quantify Multiplexed Immune-Oncology Markers and Compare with Corresponding Monoplexed Samples

Kristin Wilson<sup>1</sup>, Ciara Martin<sup>1</sup>, Joshua Black<sup>1</sup>, Nathan Martin<sup>1</sup>, Logan Cerkovnik<sup>1</sup>, Jasmeet Bajwa<sup>1</sup>, Carsten Schnatwinkel<sup>1</sup>, Daniel Rudmann<sup>1</sup>, Anthony Milici<sup>1</sup>, <sup>1</sup>Flagship Biosciences, Westminster, CO, US

## 51 Feline Mammary Cancer: Novel Nude Mouse Model and Molecular Characterization of Invasion and Metastasis Genes

Bardes Hassan<sup>1,2</sup>, Said Elshafae<sup>1,3</sup>, Wachiraphan Supsavhad<sup>1</sup>, Jessica Simmons<sup>1</sup>, Wessel Dirksen<sup>1</sup>, Sohair Sokkar<sup>2</sup>, Thomas Rosol<sup>1</sup>, <sup>1</sup>The Ohio State University, Columbus, Ohio, US, <sup>2</sup>Cairo University, Giza, Egypt, <sup>3</sup>Benha University, Kalyubia, Egypt

## 52 Suppression of Osteopontin Inhibits Chemically Induced Hepatocarcinogenesis by Induction of Apoptosis

Su-Hyung Lee<sup>1</sup>, Jun-Won Park<sup>2</sup>, Du-Min Go<sup>1</sup>, Hyo-Jung Kwon<sup>3</sup>, Dae-Yong Kim<sup>1</sup>, <sup>1</sup>Seoul National University, Seoul, Republic of Korea, <sup>2</sup>National Cancer Center, Goyang, Gyeonggi, Republic of Korea, <sup>3</sup>Chungnam National University, Daejeon, Republic of Korea

## 53 Induction of Oxidative Stress and DNA Adduct Formation in A549 and BEAS-2B Cells by Cobalt (II) Sulfate Heptahydrate

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## 54 Immunohistochemical Characterization of Islets of Langerhans in F344/N Rats Exposed to Cobalt (II) by Inhalation

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## 55 Thymomas in Fischer 344/N Rats in the National Toxicology Program Database

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## 56 Comparison of Proliferative Biliary Lesions in F344 Rats and Humans

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## 57 CLL1-Targeting Nanomicelles Containing Daunorubicin Have Anti-Leukemia Stem Cell Activity in Patient-Derived Xenograft Models of Acute Myeloid Leukemia

Tzu-yin Lin<sup>1,2</sup>, Yanjun Zhu<sup>1</sup>, Yuanpei Li<sup>1</sup>, Susan Airhart<sup>3</sup>, Chong-Xian Pan<sup>1</sup>, Brian Jonas<sup>1</sup>, <sup>1</sup>UC Davis, Sacramento, CA, US, <sup>2</sup>LP Therapeutics, Davis, CA, US, <sup>3</sup>Jackson Lab, Bar Harbor, ME, US

**58 Processing of Guinea Pig Inner Ear for Histopathological Evaluation**

Jean-Francois Lafond<sup>1</sup>, Elena Bota<sup>1</sup>, Natalie Dolinsek<sup>1</sup>, Nathalie Lamer<sup>1</sup>, Andrea-Claude Laroche-Connelly<sup>1</sup>, Claudine Savard<sup>1</sup>, Manon Skelling<sup>1</sup>, Kelly Tenneson<sup>1</sup>, Pierre Tellier<sup>1</sup>, <sup>1</sup>Charles River Laboratories, Senneville, Quebec, Canada

**59 Histopathology of a Mouse Model of Kanamycin/Furosemide-Induced Cochlear Hair Cell Injury**

Jean-Francois Lafond<sup>1</sup>, Kelly Tenneson<sup>1</sup>, Gayle Hennig<sup>1</sup>, Pierre Tellier<sup>1</sup>, <sup>1</sup>Charles River Laboratories, Senneville, Quebec, Canada

**60 Changes in Plasma Adrenal Steroids and in Adrenal Histology in Rats Reflecting Modes of Action of Compounds on Adrenal Steroidogenesis**

Tomoaki Tochitani<sup>1</sup>, Akihito Yamashita<sup>1</sup>, Mami Kouchi<sup>1</sup>, Yuta Fujii<sup>1</sup>, Izumi Matsumoto<sup>1</sup>, Izuru Miyawaki<sup>1</sup>, Toru Yamada<sup>1</sup>, Takatoshi Koujitan<sup>1</sup>, <sup>1</sup>Sumitomo Dainippon Pharma Co., Ltd., Osaka, Japan

**61 Effects of Unilateral Nephrectomy on Diabetic Kidney Lesions in db/db Mice**

Kaoru Toyoda<sup>1</sup>, Kochi Kakimoto<sup>1</sup>, Katsuhiko Miyajima<sup>1</sup>, Yuzo Yasui<sup>1</sup>, Yusuke Kemmochi<sup>1</sup>, Akiko Anagawa-Nakamura<sup>1</sup>, Eriko Riya<sup>1</sup>, Akemi Takahashi<sup>1</sup>, Toshiyuki Shoda<sup>1</sup>, Kayoko Takagi<sup>1</sup>, Satomi Takeuchi<sup>1</sup>, Tatsuya Maekawa<sup>1</sup>, Yoshifumi Miyakawa<sup>1</sup>, <sup>1</sup>Japan Tobacco Inc., Kanagawa, Japan

**62 Maturity-Related Variability of the Thymus in Cynomolgus Monkeys (*Macaca fasciculata*)**

Nancy Everts<sup>2</sup>, Paul Snyder<sup>1</sup>, William Craven<sup>2</sup>, Jonathan Werner<sup>3</sup>, Sarah Tannehill-Gregg<sup>3</sup>, Roberto Guzman<sup>3</sup>, <sup>1</sup>Experimental Pathology Laboratories, Inc, West Lafayette, IN, US, <sup>2</sup>Amgen, South San Francisco, CA, US, <sup>3</sup>Amgen, Thousand Oaks, CA, US

**63 Postnatal Development of the Rat Kidney**

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**64 Glial Fibrillary Acidic Protein-Positive Glial Tumors Do Occur in Harlan Sprague-Dawley Rats**

Kyathanahalli Janardhan<sup>1</sup>, Ramesh Kovi<sup>2</sup>, Arun Pandiri<sup>3</sup>, David Malarkey<sup>3</sup>, Mark Cesta<sup>3</sup>, Robert Sills<sup>3</sup>, Amy Brix<sup>2</sup>, Gordon Flake<sup>3</sup>, Ron Herbert<sup>3</sup>, Paul Foster<sup>3</sup>, Susan Elmore<sup>3</sup>, <sup>1</sup>Integrated Laboratory Systems Inc., Research Triangle Park, NC, US, <sup>2</sup>Experimental Pathology Laboratories Inc., Research Triangle Park, NC, US, <sup>3</sup>National Toxicology Program, NIEHS, Research Triangle Park, NC, US

**65 Two Morphologic Different Variants of Immune Complex-Mediated Endocapillary Glomerulonephritis in Cynomolgus Monkeys**

Juergen Funk<sup>1</sup>, Jennifer Rojko<sup>2</sup>, Marie-Anne Marten<sup>3</sup>, Christine Schubert<sup>1</sup>, Thomas Sergejew<sup>1</sup>, Michael J Mihatsch<sup>4</sup>, <sup>1</sup>Roche Pharmaceutical Research and Early Development, Pharmaceutical Sciences, Roche Innovation Center Basel, Basel, Switzerland, <sup>2</sup>Charles River Pathology Associates, Frederick, MD, US, <sup>3</sup>Charles River Tranent, Edinburgh, UK, <sup>4</sup>University Hospital Basel, Institute for Pathology, Basel, Switzerland

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Bettina Lawrenz<sup>1</sup>, Christina Elliott<sup>1</sup>, Ludwig Schladt<sup>1</sup>, <sup>1</sup>Bayer Pharma AG, Wuppertal, Germany

**67 Retinal Lesion and miRNA Elevation Induced by UNC569, a MerTK Inhibitor, in Mice**

Ayako Sayama<sup>1</sup>, Tetsuya Ohsawa<sup>1</sup>, Keiko Okado<sup>2</sup>, Koichi Nakamura<sup>3</sup>, Takuma Iguchi<sup>1</sup>, Toshihiko Makino<sup>1</sup>, Kiyonori Kai<sup>1</sup>, Wataru Takasaki<sup>1</sup>, <sup>1</sup>Medicinal Safety Research Laboratories, Daiichi Sankyo Co., Ltd., Edogawa-ku, Tokyo, Japan, <sup>2</sup>Discovery Science & Technology Department, Daiichi Sankyo RD Novare Co., Ltd., Edogawa-ku, Tokyo, Japan, <sup>3</sup>Drug Metabolism & Pharmacokinetics Research Laboratories, Daiichi Sankyo Co., Ltd., Shinagawa-ku, Tokyo, Japan

**68 Toxicity Study in Cynomolgus Monkeys to Understand the Pathogenesis of Drug-Induced Thrombocytopenia**

William Reagan<sup>1</sup>, Theodore Schmahai<sup>1</sup>, Norimitsu Shirai<sup>1</sup>, Frank Geoly<sup>1</sup>, Carlin Okerberg<sup>1</sup>, Gregg Cappon<sup>1</sup>, Sharon Sokolowski<sup>1</sup>, Chunli Huang<sup>1</sup>, Cynthia Drupa<sup>1</sup>, Walt Bobrowski<sup>1</sup>, Laurel VanDerWiele<sup>1</sup>, Kenneth Kelly<sup>2</sup>, William Esler<sup>2</sup>, <sup>1</sup>Pfizer, Groton, CT, US, <sup>2</sup>Pfizer, Cambridge, MA, US

**69 Rat Models of IL-23 or Imiquimod-Induced Inflammation as Translational Tools for Psoriasis Drug Discovery**

Sheila Cummings Macri<sup>1</sup>, Robert Resnick<sup>1</sup>, Kyriakos Economides<sup>1</sup>, Lan Gao<sup>1</sup>, Erik Zarazinski<sup>1</sup>, Errin Roberts<sup>1</sup>, Kuldeep Singh<sup>1</sup>, Sandra Dinocca<sup>1</sup>, Arun Subramanian<sup>1</sup>, Beth Thurberg<sup>1</sup>, Dinesh Bangari<sup>1</sup>, <sup>1</sup>Sanofi Genzyme, Framingham, MA, US

**70 BTK Knockout Rat Model Demonstrates Rat-Specific BTK Inhibitor-Related Pancreatic Pathology Is On-Target and Unlikely to Be Relevant for Humans**

Leah Schutt<sup>1</sup>, Rebecca Erickson<sup>1</sup>, Jacqueline Tarrant<sup>1</sup>, Michelle McDowell<sup>1</sup>, Arna Katewa<sup>1</sup>, Yugang Wang<sup>1</sup>, Tao Huang<sup>1</sup>, William Kennedy<sup>1</sup>, Dinah Misner<sup>1</sup>, Karin Reif<sup>1</sup>, <sup>1</sup>Genentech, Inc., South San Francisco, CA, US

**71 Aseptic Meningitis in Mice Following Intravenous Administration of a T Cell-Targeting Antibody**

Dinesh Bangari<sup>1</sup>, Patrick Finn<sup>1</sup>, Emily LaCasse<sup>1</sup>, Tanya Walker<sup>1</sup>, Gina LaCorcia<sup>1</sup>, Carla Lawendowski<sup>1</sup>, Mark Blazka<sup>1</sup>, Alison McVie-Wylie<sup>1</sup>, Beth Thurberg<sup>1</sup>, <sup>1</sup>Sanofi Genzyme, Framingham, MA, US

**72 Focal Chondrocyte Dysplasia in the Femoral Metaphysis in Young Sprague-Dawley Rats**

Noriaki Ishigami<sup>1</sup>, Koji Shimouchi<sup>2</sup>, Ai Hashimoto<sup>1</sup>, Jun Katagi<sup>1</sup>, <sup>1</sup>ONO Pharmaceutical Co., Ltd, Shimamoto-cho, Osaka, Japan, <sup>2</sup>ONO Pharmaceutical Co., Ltd, Sakai-shi, Fukui, Japan

## 73 **INHAND: International Harmonization of Nomenclature and Diagnostic Criteria for Lesions—An Update—2016**

Charlotte Keenan<sup>1</sup>, Julia Baker<sup>2</sup>, Alys Bradley<sup>3</sup>, Dawn Goodman<sup>4</sup>, Takanori Harada<sup>5</sup>, Ronald Herbert<sup>6</sup>, Wolfgang Kaufmann<sup>7</sup>, Rupert Kellner<sup>8</sup>, Beth Mahler<sup>6</sup>, Emily Meseck<sup>9</sup>, Thomas Nolte<sup>10</sup>, Suzanne Rittinghausen<sup>8</sup>, John Vahle<sup>11</sup>, Katsuhiko Yoshizawa<sup>12</sup>, <sup>1</sup>CM Keenan ToxPath Consulting, Doylestown, PA, US, <sup>2</sup>Charles River, Frederick, MD, US, <sup>3</sup>Charles River, Tranent, Scotland, UK, <sup>4</sup>Independent Consultant, Potomac, MD, US, <sup>5</sup>The Institute of Environmental Toxicology, Joso-shi, Ibaraki, Japan, <sup>6</sup>NIEHS, Research Triangle Park, NC, US, <sup>7</sup>Merck KGaA, Darmstadt, Germany, <sup>8</sup>Fraunhofer ITEM, Hanover, Germany, <sup>9</sup>Novartis Institute for Biomedical Research, East Hanover, NJ, US, <sup>10</sup>Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss, Germany, <sup>11</sup>Eli Lilly & Company, Indianapolis, IN, US, <sup>12</sup>Kansai Medical University, Hirakata, Osaka, Japan

## 74 **Drug-Induced Retinal Toxicity and Associated Changes in the Optic Tract of Laboratory Beagles**

Gail Pearse<sup>1</sup>, Peter Clements<sup>1</sup>, <sup>1</sup>GSK, Ware, Hertfordshire, UK

## 75 **Pathologic Features of Generalized Amyloidosis in a Cynomolgus Monkey (*Macaca fascicularis*)**

Meliton Novilla<sup>1,3</sup>, Mark Cottingham<sup>2</sup>, George De Los Santos<sup>1</sup>, E Bruce Bernacky<sup>2</sup>, Stewart Jacobson<sup>1</sup>, <sup>1</sup>SNBL USA Ltd, Everett, WA, US, <sup>2</sup>SNBL USA SRC, Alice, TX, US, <sup>3</sup>Purdue University, School of Veterinary Medicine, West Lafayette IN, US

## 76 **The Route of Exposure Influences Nasal Lesion Distribution in Rats in NTP Studies**

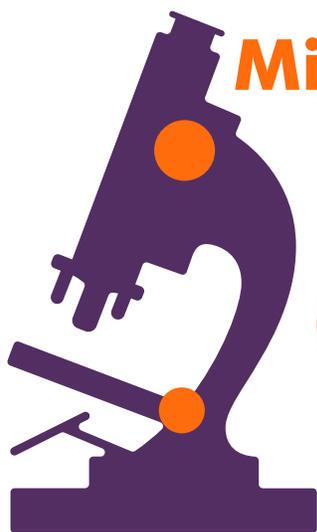
Rodney A. Miller<sup>1</sup>, Rebecca R. Moore<sup>2</sup>, Karen Y. Cimon<sup>1</sup>, Gabrielle A. Willson<sup>1</sup>, Arun R. Pandiri<sup>3</sup>, David E. Malarkey<sup>3</sup>, <sup>1</sup>Experimental Pathology Laboratories, Inc., Research Triangle Park, NC, US, <sup>2</sup>Integrated Laboratory Systems, Research Triangle Park, NC, US, <sup>3</sup>Cellular and Molecular Pathology Branch, Division of the National Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, US

## 77 **Cytological Bone Marrow Cell Differential Counts and Morphologic Findings in Healthy Cynomolgus Monkeys (*Macaca fascicularis*) from Nonclinical Toxicology Studies**

Caitlyn Carter<sup>1</sup>, Laura Cregar<sup>1</sup>, Adam Aulbach<sup>1</sup>, <sup>1</sup>MPI Research, Mattawan, MI, US

## 78 **Tetrabromobisphenol A Induces Cell Proliferation, Leptin Expression, and Leptin Receptor Phosphorylation in Human Uterine Leiomyoma Cells**

Lysandra Castro<sup>1</sup>, Alicia Moore<sup>1</sup>, Linda Yu<sup>1</sup>, Xiaohua Gao<sup>2</sup>, Darlene Dixon<sup>1</sup>, <sup>1</sup>Molecular Pathogenesis Group, National Toxicology Program Laboratory (NTPL), National Toxicology Program (NTP), National Institute of Environmental Health Sciences (NIEHS), Research Triangle Park, NC, US, <sup>2</sup>DS Technologies, Incorporated, Morrisville, NC, US



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Exhibit Hall—Grand Hall C

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### Tuesday, June 28

#### Break

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## Exhibitor-Hosted Session

### Tuesday, June 28

#### Visiopharm

12:15 PM–1:15 PM

Cortez Hill B

Advance registration is requested.

#### **Increase Efficiency, Decrease Bias in Image Analysis and What to Do When You Can't**

Delivered by Dr. Danielle Brown, of WIL Research

Two-dimensional image analysis is an efficient way to obtain quantitative information about tissue sections. However, it makes several assumptions, which are sources of bias. This talk will focus on ways to decrease this bias while increasing efficiency through the use of whole-slide imaging and unbiased sampling methods. In addition, the talk will illustrate ways in which image analysis can be combined with stereology to further reduce bias.

# 35<sup>TH</sup> ANNUAL SYMPOSIUM

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## Society of Toxicologic Pathology

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Founded in 1971, the Society Toxicologic Pathology (STP) is a nonprofit association of pathologists and other scientists whose principal aim is the advancement of pathology as it pertains to changes elicited by pharmacological, chemical and environmental agents, and factors that modify these responses. The Society's Vision: Be an international leader for improvement of human, animal, and environmental health using an interdisciplinary scientific approach based in pathology and toxicology. This vision will be accomplished through four primary goals: advocacy, education, globalization, and recruitment.

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Tourisme Montréal, a private, nonprofit organization comprised of more than 750 members and partners from Montréal's tourism industry, who share the common goal of promoting the city as a premier travel destination to non-local markets. We look forward to welcoming STP 36th Annual Symposium, June 24–29, 2017.

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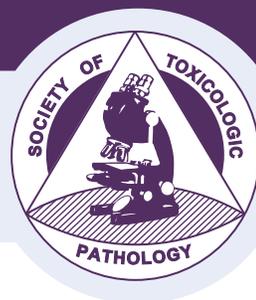
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