

STP 45TH ANNUAL SYMPOSIUM

The Pulse of Progress: Advancing Knowledge on
Cardiovascular Toxicity

San Diego, California, June 21–24, 2026
Paradise Point



SUNDAY, JUNE 21

STP Satellite Symposium

9:00 AM–12:00 Noon

Chair: Erin Quist, DVM, MS, PhD, DACVP, Charles River Laboratories, Inc.

Co-Chair: Katie Heinz-Taheny, DVM, PhD, DABT, DACVP, Eli Lilly and Company

The objective of this interactive symposium is to provide continuing education on interpreting pathology slides and data, 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, and the results will be displayed on the screen. Time is allowed for discussion after each voting session.

CE1

1:30 PM–5:00 PM

Beyond the Dipstick: Urinalysis as a Tool for In Depth Assessment of the Renal Structure and Function

Co-Chairs: Susan Emeigh Hart, VMD, PhD, DACVP, DABT, ERT, Venatorx Pharmaceuticals, Inc; and Allison Vitsky, DVM, DACVP, Pfizer, Inc.

The kidney is one of the few organs whose functional and structural integrity can be directly evaluated by non-invasive collection and evaluation of its direct output—urine. Urinalysis is included in most standard toxicology studies, but the quantity, quality and interpretation of information obtained is frequently constrained by variability in sample collection and handling, test methodology and the limitations of semi-quantitative evaluation of multiple parameters from the use of colorimetric reagent test strips (“dipsticks”) developed for human urine. These constraints have resulted in controversy regarding the usefulness of including urinalysis in routine studies. The purpose of this CE course is to provide the participants with tips on how to maximize the information obtained from routine urinalysis and incorporate some additional urinalysis parameters “beyond the dipstick” to obtain deeper insight into the effects on test compounds on renal function and integrity.

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| 1:30 PM–1:35 PM | Course Overview and Speaker Introductions
<i>Allison Vitsky, DVM, DACVP, Pfizer, Inc.</i> |
| 1:35 PM–2:15 PM | Mining Liquid Gold: Maximizing the Data from Urinalysis in Nonclinical Toxicity Studies
<i>Laura I. Boone, DVM, PhD, DACVP, DABT, Labcorp, Inc.</i> |
| 2:15 PM–2:55 PM | Pitfalls of Urine Evaluation in Nonclinical Studies
<i>Florence Poitout-Belissent, DVM, DACVP, DECVP, Charles River Laboratories</i> |
| 2:55 PM–3:25 PM | Break |
| 3:25 PM–4:05 PM | Urinalysis as a Non-Invasive Tool for Renal Functional Assessment
<i>Susan Emeigh Hart, VMD, PhD, DACVP, DABT, ERT, Venatorx Pharmaceuticals, Inc</i> |
| 4:05 PM–4:45 PM | Urinalysis as a Tool for Non-Invasive Renal Tubular Injury
<i>Adeyemi Adedeji, DVM, PhD, DACVP, Genentech</i> |
| 4:45 PM–5:00 PM | Panel Discussion |

Welcome Reception

5:30 PM–7:00 PM

MONDAY, JUNE 22

STP 45th Annual Symposium Welcome

8:00 AM–8:10 AM

Keynote Presentation

8:10 AM–9:10 AM

Stem Cells, Genomics, and AI: From Precision Medicine to Clinical Trials in Dish

Joe Wu, MD, PhD, Stanford University

Session 1

9:10 AM–12:00 Noon

Patient-Focused Cardiovascular Safety Assessment: Enhancing Translation

Co-Chairs: Brian Berridge, DVM, PhD, DACVP, B2 Pathology Solutions LLC.; and Kathy Gabrielson, DVM, PhD, Johns Hopkins University

Cardiovascular disease is a significant source of patient morbidity and mortality in most parts of the world. Accordingly, there is considerable investment and effort in the discovery and development of novel CV medicines as well as interest in the CV liabilities of drugs and environmental exposures.

Despite a robust preclinical safety assessment paradigm that most often protects patients from severe unintended harm, CV liabilities continue to be a challenging source of drug development attrition. Also, we recognize that our ubiquitous exposures to chemicals in our environment contributes to the onset, progression, and severity of human CV disease. Our ability to protect patients and non-patients from adverse CV effects of drugs and environmental exposures depends on our understanding, our ability to model, and our ability to detect and manage those effects in patients.

This opening session will establish a foundational understanding of the links between clinical CV disease and the way we model and characterize it preclinically. We will explore the emergence of novel human-derived modeling systems and how they are being used to discover and develop new therapies. We'll review current approaches to assessing drug and environmental safety liabilities identifying strengths and weaknesses. We'll learn about clinical efforts to identify patients experiencing these liabilities as well as contemporary environmental CV risks.

The aim of this session is to provide a basis for learning more about the innovative ways that CV safety liabilities are being evaluated in pre-clinical drug and environmental safety assessment.

9:10 AM–9:45 AM **Cardiovascular Safety Assessment: Building Translational Bridges**
Brian Berridge, DVM, PhD, DACVP, B2 Pathology Solutions LLC.

9:45 AM–10:15 AM **Break**

10:15 AM–10:50 AM **Cardio-Oncology: Bench to Bedside**
Javid Moslehi, MD, University of California, San Francisco

10:50 AM–11:25 AM **Domoic Acid Cardiotoxicity in California Sea Lions**
Maggie Martinez, DVM, MS, PhD, DACVP, The Marine Mammal Center

11:25 AM–11:45 AM **Student Speaker**

11:45 AM–12:00 Noon **Student Speaker**

Session 2

1:30 PM–5:00 PM

Integrated Cardiovascular Safety Assessment—Collaboration with Safety Pharmacology

Co-Chairs: Rebecca Kohnken, DVM, PhD, DACVP, Abbvie; Hugo Vargas, PhD, DSP, Amgen Inc.

The Monday afternoon session will introduce the concept of an integrated cardiovascular safety assessment which combines the morphologic and functional endpoints available from preclinical studies. In collaboration with Safety Pharmacology colleagues, the session will provide an overview of *in vitro* and *in vivo* functional safety assessments conducted by safety pharmacologists, highlighting the value of these data for toxicologists and pathologists. Particular emphases on secondary pharmacology and *in vivo* endpoints evaluation will provide a deeper dive into these hot topics. Case examples will be provided that highlight the importance of this integrated approach. Wrapping up the session, an overview of the current state of regulatory emphasis on New Approach Methodologies (or NAMs) will key up the remainder of the topics over the subsequent two days of cutting-edge science.

1:30 PM–1:35 PM **Introduction**
Hugo Vargas, PhD, DSP, Amgen Inc.

THE PULSE OF PROGRESS: ADVANCING KNOWLEDGE ON CARDIOVASCULAR TOXICITY

- 1:35 PM–2:15 PM **Safety Pharmacology Strategies: Practical Deconvolution and Decision Pathways**
Sridharan Rajamani, PhD, The Janssen Pharmaceutical Companies of Johnson & Johnson
- 2:15 PM–3:00 PM **Integration of a Nonclinical Cardiovascular Safety Assessment**
Rebecca Kohnken, DVM, PhD, DACVP, AbbVie
- 3:00 PM–3:30 PM **Break**
- 3:30 PM–4:05 PM **Cardiovascular Safety Pharmacology Integration into Toxicology Studies: A Review of What We Learned, Where We Are Now, and Futures Aims**
Steve Tichenor, PhD, Charles River Laboratories; and Derek Leishman, PhD, Eli Lilly & Company
- 4:05 PM–4:40 PM **Integrating Secondary Pharmacology Data to Assess Cardiovascular Risk of Novel Compounds**
Kim Henderson Park, PhD, DABT, Amgen
- 4:40 PM–5:00 PM **Regulatory Landscape for Preclinical NAMs in Drug Development**
Samantha Atkins, PhD, Moderna

Annual Business Meeting and Town Hall

5:30 PM–7:00 PM

TUESDAY, JUNE 23

Session 3

8:00 AM–12:00 Noon

Re-Examining Nonclinical Cardiovascular Safety Assessment in Drug Development

Co-Chairs: Heath Thomas, DVM, PhD, DACVP, Aclairo; Todd Bourcier, PhD, White Oak Regulatory Tox, LLC.

This session will explore emerging and persistent challenges in cardiovascular safety assessment, particularly in areas that warrant renewed attention. Topics will include the complexities of evaluating vascular injury, drug-mediated cardiotoxicity, coagulation and prothrombotic risk, and broader considerations of drug attrition attributable to cardiovascular safety liabilities. In addition, the session will provide a brief update on current INHAND terminology, and emphasize the case for modernizing cardiovascular safety testing strategies under ICH S7A. By bringing these issues forward, the session aims to engage the STP community in shaping future directions for cardiovascular safety evaluation.

- 8:00 AM–8:50 AM **Session Introduction and Challenges in Drug Development with Cardiovascular Toxicity**
Heath Thomas, DVM, PhD, DACVP, Aclairo
- 8:50 AM–9:25 AM **Heart of the Matter: Herceptin, Small Molecules, and a New Era of Cardiotoxicity**
Noel Dybdal, DVM, PhD, DACVP, DACAW, Genentech
- 9:25 AM–10:00 AM **Assessing the Value of Nonclinical Testing to Predict Cardiovascular Toxicity**
Thomas Monticello, PhD, DACVP, Hillock Nonclinical Consulting
- 10:00 AM–10:30 AM **Break**
- 10:30 AM–11:10 AM **Points to Consider for Revising the ICH S7A Guideline on Safety and Secondary Pharmacology**
Derek Leishman, PhD, Eli Lilly & Company
- 11:10 AM–11:25 AM **What's In a Name? An Update on INHAND CV Terminology**
Brian Berridge, DVM, PhD, DACVP, B2 Pathology Solutions, LLC.
- 11:25 AM–12:00 Noon **Translational Biomarkers of Prothrombotic Imbalance**
Cindy Fishman, VMD, PhD, GlaxoSmithKline

STP 45TH ANNUAL SYMPOSIUM

Committee Social

12:00 Noon–1:30 PM

CDOC Tuesday

1:30 PM–5:00 PM

Career Development Workshop

The Path Ahead: Strategies for Wellbeing, Resilience, and Career Evolution

Co-Chairs: *Jessica Grieves, DVM, PhD, DACVP, Johnson & Johnson Innovative Medicine; and Nicholas Vetter, DVM, DACVP, Inotiv*

Change is inevitable—but it doesn't have to be overwhelming. Career transitions in toxicologic pathology can feel intimidating, whether you're choosing a new path or facing unexpected challenges. This workshop offers practical strategies to turn uncertainty into opportunity. Attendees will learn how to protect their mental and physical well-being, respond to sudden employment shifts, succeed in consulting or self-employment, adapt to evolving technologies, and lead with confidence.

1:30 PM–1:35 PM	Introduction
1:35 PM–2:10 PM	Mental and Physical Wellbeing Throughout the Career
2:10 PM–2:45 PM	Voluntary or Involuntary Career Changes
2:45 PM–3:00 PM	Break
3:00 PM–3:35 PM	Self-Employment and Consulting
3:35 PM–4:10 PM	Career Development in an Evolving Industry
4:10 PM–5:00 PM	Panel: Adapting New/Changing Management Roles and Building Leadership Skills

WEDNESDAY, JUNE 24

Session 4

8:00 AM–12:00 Noon

Models in Motion: Bridging Modalities, Mechanisms, and Translation

Co-Chairs: *Vinicius Carreira, DVM, PhD, DACVP, DABT, Johnson & Johnson Innovative Medicine; and Deidre Dalmas, BS, MS, PhD, GlaxoSmithKline*

Explore the evolving landscape of therapeutic and experimental models in cardiovascular safety. This dynamic session features a panel on cutting-edge modalities—from siRNA and cell therapies to ADCs and degraders—followed by discussions on non-traditional model systems like zebrafish and pigs. Dive into biomarker strategies, emerging technologies, and regulatory updates, all aimed at enhancing translational relevance and innovation in preclinical safety science.

8:00 AM–9:30 AM	Navigating Cardiovascular Safety for Novel Modalities <i>Stephanie Klein, DVM, PhD, FTP Pathology; Ingrid Cornax, BS, Dphil, DVM, Altos Labs; and Basel Assaf, DVSc, PhD, DACVP, DABT, Sanofi</i>
9:30 AM–10:00 AM	Integrating NAMs in Cardiovascular Safety: New Opportunities for Enhanced Risk Assessment <i>Sébastien Laurent, DVM, DESV-AP, Dipl. ECVP, Sanofi</i>
10:00 AM–10:30 AM	Break
10:30 AM–11:05 AM	Vascular Toxicity Associated with Novel Modalities: Biomarker Strategies for Detection and Monitoring <i>Allison Vitsky, DVM, DACVP, Pfizer, Inc.; and Jacqueline Tarrant, DACVP, Johnson & Johnson</i>
11:05 AM–11:40 AM	Can Plasma Cell-Free DNA and Emerging Cytokine Biomarkers Augment Standard CV Biomarkers in Prediction of Acute or Even Long-Latency Cardiotoxicity? <i>Kathy Gabrielson, DVM, PhD, Johns Hopkins University</i>
11:40 AM–12:00 Noon	What's New—Evolving Consortia-Driven Approaches to Cardiovascular Risk Assessment and Biomarker Development <i>Deidre Dalmas, BS, MS, PhD, GlaxoSmithKline</i>

THE PULSE OF PROGRESS: ADVANCING KNOWLEDGE ON CARDIOVASCULAR TOXICITY

Session 5

1:30 PM–5:00 PM

Positioning AI and NAMs for Impact in Cardiovascular Safety Assessment

Co-Chairs: Daniel Rudmann, DVM, PhD, DACVP, FIATP, Sanofi; and Michael Boyle, DVM, PhD, DACVP, FIATP, Immunome

Artificial intelligence-based methods and New Approach Methodologies (NAMs) are advancing the arsenal toxicologic pathologists have in their tool kit. The objective of this session is to demystify and clarify these topics and provide examples where they are or could be used to facilitate our day-to-day work, impact 3Rs, and tackle our research questions.

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| 1:30 PM–2:15 PM | Introduction to Deep Learning and GenAI Approaches to Cardiovascular Assessment
<i>Daniel Rudmann, DVM, PhD, DACVP, FIATP, Sanofi</i> |
| 2:15 PM–3:00 PM | Predictive AI Models to Support Pathology Interpretation
<i>Debra Tokarz, DVM, PhD, DACVP, EPL, Inc.</i> |
| 3:00 PM–3:30 PM | Break |
| 3:30 PM–4:05 PM | Generative AI-Driven Quantitative Knowledge-Activity Relationships (QKARs) for Advancing Cardiotoxicity Prediction
<i>Dongying Li, PhD, US FDA</i> |
| 4:05 PM–4:40 PM | DruSaFE Perspective on Applying NAMs to Reduce Animal Use
<i>Jenna Wood, DABT, Agios Pharmaceuticals</i> |
| 4:40 PM–5:00 PM | Cancer Therapy-Associated Cardiomyopathy
<i>Anna Narezkina, MD, UCSD Cardiovascular Institute</i> |

Awards and Recognition Ceremony

5:30 PM–6:30 PM

President's Reception

7:00 PM–9:00 PM