Society for Birth Defects Research and Prevention (BDRP)
65th Annual Meeting
Researching New Heights in Birth Defects Research: Fundamentals to Cutting-Edge Research
Hilton Denver City Center, Denver, CO
June 28–July 2, 2025

Concurrent with the annual meetings of the Developmental Neurotoxicology Society (DNTS), National Birth Defects Prevention Network (NBDPN), and Organization of Teratology Information Specialists (OTIS)

As of July 2, 2025
The times listed are in Mountain Daylight Saving Time.

Saturday, June 28, 2025

7:30 AM–5:00 PM **Registration Open**

8:00 AM–8:30 AM **Education Course Coffee and Pastries**
(Education Course Session 1 Registrants Only)

8:30 AM–12:00 Noon **The Principles of Teratology**
Education Course 1
(Separate Registration Required)

Organized by the BDRP Education Committee

Chairperson: Ronee Baracani, Eli Lilly and Company

This course will focus on the principles of teratology and their application. Topics addressed will include the timeline of important events in embryo-fetal development across species; direct and indirect causes of developmental toxicity, including those of maternal, fetal, and placental origin; the common pathways and mechanisms by which teratogens may act; how developmental toxicants are typically detected through studies conducted in animals; and how epidemiological studies contribute to the detection of potential teratogens.

8:30 AM–8:35 AM	Welcome *BDRP Vice President, Prägati S. Coder, Charles River Laboratories, Ashland LLC*
8:35 AM–8:40 AM	Course Overview *Education Committee Chairperson, Ronee Baracani, Eli Lilly and Company*
8:40 AM–9:20 AM	Introduction to Wilson's Principles *Robert M. Cabrera, Baylor College of Medicine*
9:20 AM–10:00 AM	Applying Wilson's Principles in the Modern Era: Leveraging In Vitro and Omic Technologies in Developmental Biology and Toxicology *Joshua F. Robinson, University of California, San Francisco*
10:00 AM–10:15 AM	Break
10:15 AM–10:55 AM	How the Principles Apply to Nonclinical Safety Testing, Registration, and Regulations *Travis L. Calkins, Charles River Laboratories, Ashland*
10:55 AM–11:35 AM	How the Principles of Teratology Apply to Clinical and Epidemiology Research *Sonja A. Rasmussen, Johns Hopkins School of Medicine*

11:35 AM–12:00 Noon Discussion

1:30 PM–5:00 PM **The ABCs of EFDs: Fundamentals of Embryofetal Development Testing Education Course 2**
(Separate Registration Required)

Organized by the BDRP Education Committee

Chairpersons: Ronee Baracani, Eli Lilly and Company; Susan B. Laffan, Amgen; and Caren Villano, Boehringer Ingelheim

This course aims to discuss the principles applied to plan, deliver, and communicate embryofetal testing for pharmaceuticals in clinical development. The why, when, and how to conduct these studies and the rationale for decisions made in study design, conduct, and interpretation will be addressed. This is a course about the concepts that guide the decisions throughout the process. The first session will focus on setting the overall study strategy on which type of study, in which species, and when they should be conducted. The second session will review aspects of study design and the components of a quality study, including maternal-litter exposure and pharmacodynamic considerations. The applications of these principles to modify study designs for the testing of new modalities will be included. Followed by a session on how to manage study conduct when faced with in-life challenges (tolerability, food supplementation, rabbit abortions). Next, a session will cover the data interpretation principles specific to EFDs followed by a session on the communication of study results including when expedited reporting is required and how EFD data informs clinical protocol decisions, informed consent, and product labeling.

1:30 PM–1:35 PM	Course Overview *Education Committee Chairperson, Ronee Baracani, Eli Lilly and Company*
1:35 PM–2:10 PM	Setting the EFD Testing Study Strategy *Rüdiger Cordts, Boehringer Ingelheim Pharma GmbH & Co. KG*
2:10 PM–2:45 PM	Designing an EFD Study: Components of a Quality Study *Susan B. Laffan, Amgen*
2:45 PM–3:20 PM	Conducting an EFD Study *Denita Williams, GSK*
3:20 PM–3:35 PM	Break
3:35 PM–4:10 PM	Interpreting EFD Study Data *Bethany R. Hannas, Eli Lilly and Company*
4:10 PM–4:45 PM	Communicating EFD Study Results *Tacey E. White, Tacey White Consulting*
4:45 PM–5:00 PM	Discussion

5:00 PM–7:00 PM **BDRP Council 1 Meeting**
(All current and incoming Council members as well as current Committee Chairs and Vice Chairs attend Council 1.)

Sunday, June 29, 2025

7:00 AM–6:00 PM **Registration Open**

7:00 AM–8:00 AM ***Birth Defects Research*** **Journal Editorial Board Meeting**

7:00 AM–8:00 AM **BDRP Communications Coordination Committee Meeting**

8:00 AM–9:00 AM **Identifying Teratogens: Challenges and Opportunities**
Josef Warkany Lecture
(Joint with DNTS and OTIS)

Chairperson: Philip J. Lupo, Emory University

Sonja A. Rasmussen, Johns Hopkins School of Medicine

9:05 AM–11:40 AM **Graduate Student and Postdoctoral Fellow Wilson Presentation Award Finalists Platform Session 1**

Organized by the BDRP Student Affairs Committee

Chairperson: Deirdre K. Tucker, Crinetics Pharmaceuticals

9:05 AM–9:25 AM	Comparing Animal Developmental Toxicity to Human Pregnancy Outcomes for Fifty Pharmaceuticals: Is the Rat a Better Predictor Than the Rabbit? *Puck Roos, Medicines Evaluation Board; and Utrecht University*
9:25 AM–9:45 AM	Single-Cell Transcriptomic Profiling of Rat Embryos During Neurulation and Early Organogenesis Under Normal and Teratogenic Conditions *Lin Li, University of California, San Francisco*
9:45 AM–10:05 AM	Sex-Specific Effects of Valproic Acid on Placental Morphology in CD-1 Mice *Lauren T. L. Brown, Queen's University at Kingston*
10:05 AM–10:25 AM	High Content Imaging of Cellular Energy Metabolism to Support Chemical Safety Testing for Thyroid Disruption *Congying Wang, Michigan State University*
10:25 AM–10:40 AM	Break
10:40 AM–11:00 AM	Investigating Relationships Among PFAS During Pregnancy, Placental Gene Expression, and Adverse Pregnancy Outcomes *Mikayla Watt, University of North Carolina at Chapel Hill*
11:00 AM–11:20 AM	Building Predictive Models for Preterm Birth Among Infants with Congenital Limb Defects *Katherine L. Ludorf, The University of Texas Health Science Center at Houston*
11:20 AM–11:40 AM	Transcriptomic Analysis Reveals Mechanisms of Particulate Matter-Induced Disruption of Human Embryonic Stem Cell Osteogenesis *Madeline K.M. Vera-Colon, University of California, Irvine*

10:00 AM–6:00 PM **Poster Session 1: Unattended**
(Joint with DNTS and OTIS)

BDRP Posters P100–P125
DNTS Posters P1–P10
OTIS Posters P1–P3

12:05 PM–1:25 PM **BDRP Past Presidents' and Honorees' Luncheon**

(By Invitation Only)

12:30 PM–1:30 PM **BDRP Diversity, Equity, Inclusion, and Accessibility Committee Meeting**

12:30 PM–1:30 PM **BDRP Education Committee Meeting**

1:30 PM–2:00 PM **High Times: The Effects of Prenatal Cannabis Exposure and Next Steps**
Patricia Rodier Mid-Career Award for Research and Mentoring
(Joint with DNTS)

Organized by the DNTS and BDRP Awards Committees

Chairperson: Michael T. Williams, Cincinnati Children's Research Foundation

Natacha M De Genna, University of Pittsburgh

2:05 PM–2:35 PM **PFAS, Placenta, and Public Health: An Early Career Perspective on Communicating Science**
F. Clarke Fraser New Investigator Award

Organized by the BDRP Awards Committee

Chairperson: Cynthia J. Wolf

Bevin E. Blake

2:40 PM–3:45 PM **BDRP Innovator Award Finalists Platform Session 2**

Organized by the BDRP Awards Committee

Chairperson: Cynthia J. Wolf

Sponsored in Memory of Raymond Schroeder, MS

2:40 PM–2:45 PM	Introduction *Cynthia J. Wolf, US Environmental Protection Agency*
2:45 PM–3:05 PM	Integrative Proteomic and *In Silico* Analysis of Perfluorooctanoic Acid Exposures in Primary Human Placental Cytotrophoblasts *Mengjing Wang, University of California, San Francisco*
3:05 PM–3:25 PM	Elucidation of Adverse Outcome Pathways for Compound-Induced Developmental Neurotoxicity Using Knowledge Graphs *Ricardo Scheufen Tieghi, National Toxicology Program Interagency Center for Evaluation of Alternative Toxicological Methods (NICEATM); and University of North Carolina at Chapel Hill Eshelman School of Pharmacy*
3:25 PM–3:45 PM	An Integrative *In Vitro* and Transcriptomic Profiling Approach to Screen Environmental Chemicals for Developmental Neurotoxicity *Julia A Gomes, University of California, San Francisco*

3:45 PM–4:00 PM **Break**

4:00 PM–4:30 PM **Climate Change and Congenital Anomalies: A Population-Based Study of the Effect of Prolonged Extreme Heat Exposure on the Risk of Neural Tube Defects in France**
James G. Wilson Publication Award

Organized by the BDRP Publications Committee

Chairperson: John M. Rogers, Editor-In-Chief, Birth Defects Research

Tim A. Bruckner, University of California, Irvine

4:35 PM–6:00 PM **Multidisciplinary Research Needs Workshop**

Organized by the BDRP Science Committee

Chairpersons: Suzanne E. Fenton, NC State University; and Katie J. Turner, Janssen R&D, LLC

Discussion Topics
Birth and Pregnancy Registries: Underutilized National Treasures

- What birth registries and cohorts are currently available for research use? (Including contact information and accessible data elements)
- How are dried blood spots (DBS) being utilized to identify predictive biomarkers for birth defects and other diseases?
- Is it feasible to develop exposome profiles using dried blood spots (DBS)?

Sex-Specific Outcomes in Health Research

- Advancements and challenges in toxicity assessments related to sex-specific outcomes
- Epigenetic mechanisms, including imprinting control regions and methylation-specific profiles
- Sex-specific differences in drug metabolism and pharmacokinetics (DMPK), such as PFAS elimination patterns
- Considerations for inclusive clinical trial populations, including women, pregnant and breastfeeding individuals, and pediatric groups

Vaccinations: The Future and Impact on Healthy Babies

- Impact of COVID-19, Measles, and Influenza outbreaks on child health outcomes
- Associations between vaccinations and birth defects or newborn weight outcomes
- How can BDRP engage policymakers and influence parental attitudes to build trust in vaccinations?
- Emerging approaches for vaccine development and safety assessment in both in vivo and in vitro models

6:00 PM–7:30 PM **Poster Session 1: Poster Presentations**

(Joint with DNTS and OTIS)

BDRP Posters: P100–P125
DNTS Posters: P1–P9
OTIS Posters: P1–P3

7:30 PM–9:30 PM **Graduate Student and Postdoctoral Fellows Career Event**

Hosted by the Middle Atlantic Reproduction and Teratology Association (MARTA)

<u>Monday, June 30, 2025</u>

7:00 AM–4:30 PM **Registration Open**

8:00 AM–9:00 AM **Fetal Therapy Approaches**
Keynote Lecture
(Joint with OTIS)

Chairperson: Prägati S. Coder, Charles River Laboratories, Ashland LLC

Sarah G. Običan, University of South Florida

9:05 AM–12:00 Noon **Down Syndrome: Assessing Outcomes Across the Lifespan Symposium**

(Joint with NBDPN)

Chairpersons: Sonja A. Rasmussen, Johns Hopkins School of Medicine; and Philip J. Lupo, Emory University

Down syndrome was first recognized in 1866, and its cause (an extra copy of chromosome 21) was identified in 1958. However, the study of the co-occurring conditions seen in persons with Down syndrome remains an active area of research, stimulated in part by a new trans-NIH research initiative focusing on health and quality-of-life needs for persons with Down syndrome, called the INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE) Project. This session will discuss recent updates in surveillance and research regarding Down syndrome with speakers involved in the INCLUDE project discussing progress in this initiative. Information on conditions for which persons with Down syndrome are at increased risk (i.e., leukemia, autism, and Alzheimer's disease) and decreased risk (i.e., solid tumors) and what is known about the reasons for these differences in risk will also be discussed. This research provides insights into these conditions in the population of persons with Down syndrome, as well as the general population.

9:05 AM–9:10 AM	Introduction *Sonja A. Rasmussen, Johns Hopkins School of Medicine*
9:10 AM–9:45 AM	Breakthroughs in Down Syndrome Research in the Age of the NIH INCLUDE Project *Joaquin Espinosa, University of Colorado School of Medicine*
9:45 AM–10:20 AM	Increased Risk for Leukemia Among Children with Down Syndrome *Philip Lupo, Emory University*
10:20 AM–10:35 AM	Break
10:35 AM–11:10 AM	Co-occurring Down Syndrome and Autism Spectrum Disorder *Deborah Fidler, Colorado State University*
11:10 AM–11:45 AM	Improving the Understanding of Health Risks among Adults with Down Syndrome *Sonja A. Rasmussen, Johns Hopkins School of Medicine*
11:45 AM–12:00 Noon	Discussion

9:05 AM–12:00 Noon **Opportunities and Applications for NAMs for DART Testing from Hazard to Risk Assessment Symposium**

Chairpersons: Kristen R. Ryan, National Institute of Environmental Health Sciences; and Peter J. Boogaard, Wageningen University and Research

This session will delve into the innovative application of New Approach Methodologies (NAMs) in Developmental and Reproductive Toxicology (DART), addressing the growing need for advanced methods to enhance regulatory decision-making and human risk assessment in developmental toxicology. First, the issues, needs, and decision frameworks of regulatory authorities for developmental toxicology will be discussed, highlighting opportunities for NAMs to streamline and improve assessments. Insight will be provided on recent guidance for validation and application, specifically regarding state-of-the-art tests for DART and how to define the applicability domain. One of the crucial issues is how in vitro test results can be translated to human biology to facilitate more informed, relevant assessments, often requiring advanced computational approaches. New developments in PBPK modeling can support the translation of concentrations that trigger responses in in vitro systems to predicted and measured human exposures. Practical examples for in silico models that allow quantitative in vitro-

in vivo extrapolation will be presented and discussed, as well as curated high-throughput screening data mapped to mechanistic target groupings and developmental toxicity modes of action. This session is designed for researchers, regulators, and industry professionals involved in developmental toxicology and risk assessment. Attendees will gain valuable insights into the latest advancements in NAMs and their practical applications in regulatory contexts, fostering novel approaches to DART testing.

9:05 AM–9:10 AM	Introduction
9:10 AM–9:45 AM	Regulatory Needs and Decision Frameworks for Developmental Toxicity: Opportunities for NAMs *Nicola Powles-Glover, ExxonMobil Biomedical Sciences, Inc.*
9:45 AM–10:20 AM	Resources to Support Validating NAMs for DART *Kristen R. Ryan, National Institute of Environmental Health Sciences*
10:20 AM–10:35 AM	Break
10:35 AM–11:10 AM	PBK Modelling to Link Human Biomonitoring Data for Marker PAHs in a Battery of *In Vitro* Test Systems Predictive for Prenatal Developmental Toxicity *Danlei Wang, Wageningen University and Research*
11:10 AM–11:45 AM	NAMs in DevTox Testing: Moving the Needle Towards Regulatory Use *Allen Kaczor, Merck & Co., Inc.*
11:45 AM–12:00 Noon	Discussion

10:00 AM–5:30 PM **Poster Session 2: Unattended**
(Joint with NBDPN)

BDRP Posters: P200–P225
NBDPN Posters: P1–P13

12:05 PM–1:45 PM **Career Development and Career Options in DART**
Professional Development Lunch Workshop
(Separate Registration Required)

Organized by the BDRP Student Affairs Committee

Chairpersons: Deirdre K. Tucker, Crinetics Pharmaceuticals; and Hao Chen, Ionis Pharmaceuticals

The Professional Development Workshop is an engaging, interactive session designed to spotlight careers in developmental and reproductive toxicology (DART). Attendees will hear from accomplished BDRP scientists at various career stages as they share their journeys in DART, the challenges they've encountered, and the key opportunities that have shaped their professional growth. Topics may include navigating career transitions, strategies for achieving work-life balance, and tips on leveraging scientific meetings to enhance professional visibility and expand networks. The workshop will conclude with a dedicated networking session, providing trainees with the chance to connect with peers and experienced scientists for personalized advice and to explore the next steps in their own DART career paths.

2:00 PM–2:30 PM **Why I Teach: Inspiring Minds and Shaping Futures**
Agnish Fellowship Lecture

Organized by the BDRP Education Committee

Chairperson: Ronee Baracani, Eli Lilly and Company

Stephen B. Harris, Stephen B. Harris Group

2:35 PM–5:30 PM **The Ripple Effect: Neonatal Abstinence Syndrome from Birth to Adolescence Symposium**
(Joint with DNTS)

Chairpersons: Melissa Beck, Cedarville University School of Pharmacy; and Wendy N. Nembhard, University of Arkansas for Medical Sciences

Neonatal abstinence syndrome (NAS) is the diagnosis given to children prenatally exposed to opiates and other drugs of abuse. With the spread of the opioid epidemic over the past 10 years, significant effort has gone into diagnosis, developing adequate treatment plans, and characterizing expected outcomes within the first few years of life. However, relatively little information exists about long-term outcomes. Additionally, relatively little information is available related to the socioeconomic impact on those outcomes. Moreover, most of the NAS literature has been conducted on children prenatally exposed to opiates, while only a small number of studies have evaluated outcomes in children exposed to other drugs of abuse. The goals of this symposium are to provide the audience with information about the effect of prenatal opioid exposure in animals in comparison to what has been observed in humans; to describe the current knowledge on short- and long-term outcomes and the approaches to treatment, and to identify gaps in the understanding of socioeconomic influences on NAS outcomes.

2:35 PM–2:40 PM	Introduction
2:40 PM–3:15 PM	Animal Models of Prenatal Opioid Exposure: What Have They Told Us? *Brittany Smith, Northern Kentucky University*
3:15 PM–3:50 PM	Neonatal Opioid Withdrawal Syndrome: Diagnosis, Treatment, and Outcomes *Jennifer McAllister, Cincinnati Children's Hospital Medical Center*
3:50 PM–4:05 PM	Break
4:05 PM–4:40 PM	Long-Term Outcomes Associated with Neonatal Abstinence Syndrome *Melissa Beck, Cedarville University School of Pharmacy*
4:40 PM–5:15 PM	Beyond Birth: The Potential Socioeconomic Influences on NAS Outcomes *Ginger Cameron, Purdue Global School of Health Sciences and Hawkeye Community College School of Science and Health Science*
5:15 PM–5:30 PM	Discussion

2:35 PM–5:30 PM **Platform Session 3**

Chairpersons: Shermaine K. Mitchell-Ryan, Health and Environmental Sciences Institute; and Connie L. Chen, Health and Environmental Sciences Institute

2:35 PM–2:51 PM	Prenatal Anti-Seizure Medication Exposure and Risk of Neurodevelopmental Disorders in Children *Loreen Straub, Brigham and Women's Hospital & Harvard Medical School*

	2:51 PM–3:07 PM	Application of Whole-Genome Preimplantation Genetic Testing to Reduce the Risk of Genetic Birth Defects *Maria Katz, Orchid*
	3:07 PM–3:23 PM	Examining the Role of the Gene *Wdfy1* in the Teratogenic Effects of Gastrulation-Stage Alcohol Exposure *Eric W. Fish, University of North Carolina, Chapel Hill*
	3:23 PM–3:39 PM	Advanced Precision: Automated Stereotaxic Intracerebroventricular (ICV) Dosing in Juvenile Rodent Models *Marcus Gerald, Charles River Labs*
	3:39 PM–3:55 PM	Interpretation of Developmental Neurotoxicity *In Vitro* Testing Battery Results in the Context of Human Exposure: Natural Compound Case Study *Paige Santos, Crop Life Europe; and Corteva Agriscience*
	3:55 PM–4:10 PM	Break
	4:10 PM–4:26 PM	Exploring New Approach Methodologies to Identify Disruption of Signaling Pathways by PFAS Exposure: Implications for Placental Dysfunction and Intrauterine Growth Restriction *Oyemwenosa Nosa Avenbuan, University of North Carolina at Chapel Hill*
	4:26 PM–4:42 PM	A Standardized High-Throughput Testing Paradigm for Assessing Spatial Learning and Memory in the Morris Water Maze in Rats *Prägati S. Coder, Charles River Laboratories, Ashland LLC*
	4:42 PM–4:58 PM	Increased Variability in Placental Morphology Following *In Utero* Benzene Exposure in Mice: Potential Implications for Differential Susceptibility and Metabolism *Megan E. Cull, Queen's University*
	4:58 PM–5:14 PM	Investigating Differentially Methylated Regions of Metabolic Genes in Embryonic Fish Cells Following Exposure to the Flame Retardant Triphenyl Phosphate Using Whole Genome Bisulfite Sequencing *Logan S. Germain, Queen's University*
	4:14 PM–5:30 PM	BOOST-HP DrugScan: Identifying Medications Associated with Pregnancy Loss Using Data-Mining Techniques *Judith C. Maro, Harvard Medical School and Harvard Pilgrim Health Care Institute*

5:30 PM–7:00 PM **Poster Session 2: Poster Presentations**
(Joint with NBDPN)

BDRP Posters: P200–P225
NBDPN Posters: P1–P13

Tuesday, July 1, 2025

7:00 AM–8:00 AM **BDRP Awards Committee Meeting**

7:00 AM–8:00 AM **BDRP Student Affairs Committee Meeting**

7:00 AM–8:00 AM **BDRP Science Committee Meeting**

7:30 AM–3:30 PM **Registration Open**

8:00 AM–9:00 AM **Accelerating Clinical Development for Maternal-Fetal Health: Ensuring Access to Safe and Effective Medicines for All**
Robert L. Brent Lecture—Teratogen Update
(Joint with DNTS and OTIS)

Chairperson: Prägati S. Coder, Charles River Laboratories, Ashland LLC

Vani Vannappagari, ViiV Healthcare

9:05 AM–12:00 Noon **Birth Defects and Reproductive Issues in Post-Dobbs vs. Women's Health Organization Era Symposium**
(Joint with DNTS and OTIS)

Organized by the BDRP Public Affairs Committee

Chairpersons: Vijaya Kancherla, Emory University Rollins School of Public Health; and Sarah G. Običan, University of South Florida

The 2022 Supreme Court decision in the Dobbs v. Jackson Women's Health Organization has resulted in laws banning or limiting access to abortion services in many states in the US. The decision has impacted reproductive health care beyond abortion access, affecting both the physical and mental health of women, disproportionately impacting women of color and those in underserved communities, while intruding on clinical decision-making and affecting the doctor-patient relationship. The Society for Birth Defects Research and Prevention published a statement upholding reproductive health rights, access to necessary services, and information to make informed decisions on reproductive health, in conjunction with healthcare professionals. The Public Affairs Committee symposium aims to present the situation related to birth defects and reproductive health in the post-Dobbs era, with presentations focusing on 1) the implications of the ruling on birth defects surveillance methods; 2) obstetric clinical practice of healthcare professionals providing care for birth defects; 3) ethical complexities in conducting teratology research, including risks for research participants and staff, contributing to new challenges to scientific validity and feasibility of birth defects research; and 4) disparities in health service utilization and health policy implementation perspective for reproductive health.

9:05 AM–9:10 AM	Introduction
9:10 AM–9:45 AM	Implications of Abortion Legislation on Birth Defects Surveillance *Amanda L. Elmore, University of South Florida*
9:45 AM–10:20 AM	Obstetric Clinical Perspectives in the Post-Dobbs Era *Sarah G. Običan, University of South Florida*
10:20 AM–10:35 AM	Break
10:35 AM–11:10 AM	Ethical Challenges in the Post-Dobbs Era *Christine P. Curran, Northern Kentucky University*
11:10 AM–11:45 AM	Why We Need Segmentation of Data in Medical Records and Why We Might Not Want It *Timothy Wen, University of California, San Diego*
11:45 AM–12:00 Noon	Discussion

12:05 PM–1:45 PM **Genomics and Multi-omic AI Applications for Birth Defect Research Lunch and Learn Mini Course**
(Separate Registration Required)

Organized by the BDRP Education Committee

Chairperson: Ronee Baracani, Eli Lilly and Company

Sponsored by Argus International Inc.

This course will focus on AI in genomics and multi-omics. Attendees can expect a practical perspective with a focus on learning how to integrate AI applications into their work. The first half of this mini course will delve into areas including genome-wide interrogations, leveraging relevant databases, and noncoding variation. The second half of the course will focus on multimodal AI systems and AI in multi-omics including such topics as the integration of multiple data types and in situations when data is scarce, genomics and transcriptomics integration, utilizing RNAseq in combination with genomics and transcriptomics, and metagenomics.

12:05 PM–12:15 PM	Lunch Pick-Up
12:15 PM–12:50 PM	AI in Genomics *Paul Wolujewicz, School of Health Sciences, Quinnipiac University*
12:50 PM–1:25 PM	AI in Multi-omics *Vanessa Aguiar-Pulido, University of Miami*
1:25 PM–1:45 PM	Discussion

2:00 PM–5:00 PM **Integrating *In Vitro* and Computational Approaches to Identify Novel Developmental and Reproductive Toxicants and Enhance Chemical Hazard Assessments Symposium**

Chairpersons: Joshua F. Robinson, University of California, San Francisco; and Michele La Merrill, University of California, Davis

The field of toxicology is rapidly evolving, with an increasing emphasis on high-throughput systems to acquire chemical hazard data and provide crucial information for regulatory decisions. The need for efficient, accurate, and ethical methods to assess the developmental and reproductive toxicity of chemicals has driven the advancement of innovative *in vitro* and computational approaches. These methods promise to revolutionize hazard assessments by offering faster and more reliable and more reliable data acquisition compared to traditional animal testing. To fully harness these advancements, it is essential to develop frameworks that seamlessly integrate computational models/AI and *in vitro* technologies to generate relevant toxicity information. The integration of these outputs with public tools for exposure, biological activity (*in vitro* and *in vivo*), and literature databases can assist in prioritizing chemicals for further investigation and estimating potential risks more effectively. In this symposium, presentations will highlight practical applications of these integrated approaches, utilizing computational strategies combined with in vitro and nonmammalian embryo models to identify novel teratogens relevant to human exposure. The symposium will conclude with a final presenter who will provide current examples of how these data are being utilized in the regulatory arena and offer future insights.

2:00 PM–2:05 PM	Introduction
2:05 PM–2:40 PM	RosetteArray® Platform for Quantitative High-Throughput Screening of Human Neural Tube Defect Risk *Randolph S. Ashton, University of Wisconsin, Madison*

2:40 PM–3:15 PM — Characterizing Developmental Bone Toxicity in Human Embryonic Stem Cells
Nicole R. Sparks, University of California Irvine

3:15 PM–3:30 PM — Break

3:30 PM–4:05 PM — Integration of Computational Molecular Tools and Nonmammalian Models to Identify Teratogens Relevant for Human Exposure
Michele La Merrill, University of California, Davis

4:05 PM–4:40 PM — Application of *In Vitro* Data and Physiologically Based Kinetic Modeling in Developmental Neurotoxicity Hazard Identification and Chemical Risk Assessment
Anna Kreutz, Inotiv

4:40 PM–5:00 PM — Discussion

2:00 PM–5:00 PM **Genomic Studies of Birth Defects: Findings from the Centers for Birth Defects Research and Prevention Symposium**
(Joint with NBDPN)

Chairpersons: Lynn M. Almli, Centers for Disease Control and Prevention; and Paul A. Romitti, University of Iowa

The Centers for Birth Defects Research and Prevention (CBDRP) is a collaborative group of study sites investigating the causes of birth defects and how to prevent them. Ten Centers conducted the National Birth Defects Prevention Study (NBDPS), a population-based case-control study assessing genetic and non-genetic risk factors for birth defects. Pregnancy exposure data collected during a telephone interview and DNA specimens collected from more than 23,000 families have been used in a variety of analyses (e.g., candidate gene, gene-environment interaction, genome-wide association studies [GWAS], and exome sequencing).

This session will highlight results from NBDPS analyses that assessed genetic risk factors for craniosynostosis, heterotaxy, and transverse limb defects using GWAS or exome sequencing. These high-throughput analyses provided large amounts of genetic data that are helping to identify novel genes associated with birth defects and can be used in combination with pregnancy exposure data to investigate gene-environment interactions. The intended audience is conference attendees interested in learning more about this rich resource of genetic and environmental data and how they can be used to better understand and prevent birth defects.

2:00 PM–2:05 PM — Introduction
Paul A. Romitti, University of Iowa

2:05 PM–2:40 PM — Genetic Studies of Birth Defects from the Centers for Birth Defects Research and Prevention
Lynn M. Almli, Centers for Disease Control and Prevention

2:40 PM–3:15 PM — Gene Variants and Craniosynostosis: From GWAS to WGS
Paul A. Romitti, University of Iowa

3:15 PM–3:30 PM — Break

3:30 PM–4:05 PM — *In Vivo* Validation of Exome Sequencing-Derived Candidate Genes Associated with Heterotaxy in the National Birth Defects Prevention Study
Nanette Nascone-Yoder, North Carolina State University

4:05 PM–5:00 PM Discussion

5:30 PM–7:00 PM **Awards Presentations and Reception**
Graduate Student and Postdoctoral Fellow Travel Awards
Edward W. Carney Trainee Awards
Wilson Presentation Awards
James C. Bradford Memorial Student Poster Awards
Edward W. Carney Distinguished Service Award
BDRP Innovator Award
Recognition of Other Awards Presented throughout the Week

Wednesday, July 2, 2025

6:30 AM–7:30 AM **BDRP 44th Annual Volleyball Game**

7:30 AM–1:30 PM **Registration Open**

8:00 AM–9:00 AM **Are We Ready for Virtual Control Groups in DART Studies**
BDRP and European Teratology Society (ETS) Exchange Lecture

Chairpersons: Philip J. Lupo, Emory University; and Jason C. Manton, Toxiqua Ltd.

ETS
Bernd Baier, Boehringer Ingelheim Pharma GmbH & Co. KG

BDRP
Christopher J. Bowman, Pfizer Inc.

9:05 AM–12:15 PM **Advancements in Assessing the Effects of Environmental Chemicals on Maternal Health and Fetal Development Symposium**

Chairpersons: Kembra L. Howdeshell, National Institute of Environmental Health Sciences; and Paige Bommarito, US Environmental Protection Agency

Pregnancy represents a period of susceptibility for both the mother and the developing fetus. For the fetus, it is well established that aberrations in fetal development, such as fetal growth restriction, or pregnancy complications are important risk factors for adverse health outcomes during later life. Maternal health later in life is also sensitive to complications experienced during pregnancy, including pregnancy-induced hypertension or gestational diabetes. For example, women diagnosed with pregnancy-induced hypertension are at increased risk of cardiovascular disease or stroke later in life. Many factors play a role in fetal development and pregnancy health, including maternal diet, maternal and fetal epigenetics, and the endogenous hormone environment of the mother, placenta, and fetus. In addition, environmental chemical exposures, especially those with endocrine-disrupting properties, have the potential to influence these processes. This symposium presents advancements in the assessment of environmental chemicals and maternal and fetal health. Presentations include 1) the incorporation of 3-D ultrasound measurements of the fetus and assessment of non-persistent chemicals in maternal urine; 2) the influence of chemical mixtures on diverse indicators of maternal and fetal health, including biomarkers of placental development, repeated measures of maternal blood pressure during pregnancy, and non-nutritive suck behaviors in infants; 3) the role of maternal diet on the effect of environmental chemicals on maternal and fetal health outcomes; and 4) the mediating effect of the placental epigenome on the associations of environmental chemical exposures on spontaneous preterm birth and other aspects of fetal development.

9:05 AM–9:10 AM Introduction
Kembra L. Howdeshell, National Institute of Environmental Health Sciences

9:10 AM–9:45 AM	Investigating Fetal Development Using 3D Ultrasounds: Applications to Understanding the Developmental Impacts of Exposure to Endocrine Disrupting Chemicals *Danielle Stevens, National Institute of Environmental Health Sciences*
9:45 AM–10:20 AM	Prenatal Exposure to Environmental Chemical Mixtures and Maternal-Child Health Outcomes in Multiple Pregnancy and Birth Cohorts *Julia Varshavsky, Northeastern University*
10:20 AM–10:40 AM	Warkany Tea
10:40 AM–11:15 AM	The Intersecting Roles of Endocrine Disrupting Chemicals and Diet During Pregnancy for Maternal and Child Health *Rita S. Strakovsky, Michigan State University*
11:15 AM–11:50 AM	Multi-omic Data Illuminates the Placenta's Role as a Mediator Between Endocrine Disrupting Chemical Exposure and Spontaneous Preterm Birth *Alison Paquette, University of Washington*
11:50 AM–12:15 PM	Discussion

9:05 AM–12:15 PM **Neurobehavioral Testing in Nonrodent Models Used in Safety Assessment Symposium**
(Joint with DNTS)

Chairpersons: Kristina York, Charles River Laboratories; and Melissa Beck, Cedarville University School of Pharmacy

Validated methods to assess sensory functions, motor activity, and learning and memory are required to meet the minimum guideline requirements for (enhanced) pre- and postnatal developmental [(e)PPND] toxicity studies conducted according to the ICH harmonized guidelines on the detection of reproductive and developmental toxicity for human pharmaceuticals [ICH S5(R3)] as well as those intended for development pf pediatric pharmaceuticals [ICH S11]. While these studies are predominantly conducted in rodents, neurobehavioral testing is performed, albeit in a limited capacity, in alternate laboratory animal species such as nonhuman primates (NHP), rabbits, and mini-pigs. Historically, the NHP was used to support the safety assessment of biologic pharmaceuticals such as monoclonal antibodies. In recent years, with the advent of new modalities, and limited availability of NHPs, the use of alternate models such as mini-pigs and rabbits has increased significantly. This session aims to spotlight the different neurobehavioral testing methods available and in use across a broad spectrum of industry and academic experts. The session will conclude with a regulatory perspective on the data generated using these alternate models are reviewed/approached by reviewers/regulators.

9:05 AM–9:10 AM	Introduction *Kristina York, Charles River Laboratories*
9:10 AM–9:45 AM	Wisconsin General Testing Apparatus (WGTA) in Nonhuman Primates *C. Marc Luetjens, LabCorp Early Development Services GmbH*
9:45 AM–10:20 AM	Conditioned Eye Blink Reflex in Rabbits *Mark T. Herberth, Charles River*
10:20 AM–10:40 AM	Warkany Tea

10:40 AM–11:15 AM Neurobehavioral Assessments in Preterm Pigs
Helen J. K. Sable, University of Memphis

11:15 AM–11:50 AM Regulatory Aspects of Neurobehavioral Testing in Alternate Animal Models
Elizabeth Green, CDER, US FDA

11:50 AM–12:15 PM Discussion

12:30 PM–1:30 PM **BDRP Membership Committee Meeting**

12:30 PM–1:30 PM **BDRP Public Affairs Committee Meeting**

1:30 PM–4:30 PM **Minimizing Use of Nonhuman Primates for Safety Assessment of Risk to Fertility and Pregnancy Symposium**

Chairpersons: Christopher J. Bowman, Pfizer Inc.; and Ronald L. Wange, Aclairo® Pharmaceutical Development Group, Inc.

Sponsored by the Health and Environmental Sciences Institute

Nonhuman primates (NHP) are an important but limited resource to support the safety assessment of new pharmaceuticals, in particular monoclonal antibodies. The use of sexually mature NHPs are even more limited but can be used to inform the risk of infertility and adverse pregnancy outcomes. Current examples of how and why NHP have been considered important to inform developmental and reproductive toxicity (DART) risk and examples of alternative approaches, including the weight of evidence (WoE) will be presented and discussed. Specifically, a retrospective WoE analysis compared to pregnant NHP study outcomes for 65 monoclonal antibodies will be presented. A separate survey of marketed products over a 12-year span will be presented to understand how NHPs have been used to assess the risk of infertility and how it was reflected in the label. Regarding future use of NHP in DART, we will also challenge industry and regulators that WoE should be the default scenario to determine if experimental data are needed, considering non-NHP options (including standard species if appropriate) if that will inform the human risk assessment before considering the use of NHPs only if they will address data gaps not available by other means. If NHPs are needed for DART because no other available test system will provide the necessary data (e.g., pharmacological relevance) for the human risk assessment, we will offer some forward-looking considerations and recommendations for improvement. This workshop is an outcome of a HESI DART working group whose members include industry and health authority representatives from the US, Europe, and Japan.

1:30 PM–1:35 PM Introduction
Ronald L. Wange, Aclairo® Pharmaceutical Development Group, Inc.

1:35 PM–2:10 PM Current State of NHP Use Supporting Developmental and Reproductive Risk Assessment
Angela R. Stermer, Merck & Co.

2:10 PM–2:45 PM The Use of Weight-of-Evidence Approaches to Characterize Developmental Toxicity Risk for Therapeutic Monoclonal Antibodies in Humans Without *In Vivo* Studies
Hsiao-Tzu Chien, Medicines Evaluation Board

2:45 PM–3:00 PM Break

3:00 PM–3:35 PM Fertility Assessment in Nonhuman Primates: Evaluation of Marketed Products and Opportunities to Reduce Monkey Use
Puck Roos, Dutch Medicines Evaluation Board

	3:35 PM–4:10 PM	Looking Forward: Are Nonhuman Primates Needed for Developmental and Reproductive Toxicity Assessment of Pharmaceuticals? *Christopher J. Bowman, Pfizer Inc.*
	4:10 PM–4:30 PM	Discussion
4:35 PM–5:15 PM	**BDRP Annual Business Meeting**	
5:30 PM–8:00 PM	**BDRP Council 2 Meeting (2025–2026 Council members)**	