

Application of Cutting-Edge Technologies to Improve Assessment, Treatment, Prevention, and Communication regarding Birth Defects

Tucson
ARIZONA

Program Agenda

(as of 6/6/13)

FRIDAY, JUNE 21, 2013

- 3:00 PM–6:00 PM REGISTRATION—Grand Ballroom Foyer
- 3:00 PM–6:00 PM SPEAKER READY ROOM OPEN—Coronado Room
- 3:00 PM–6:00 PM COUNCIL 1A MEETING—Executive Boardroom

SATURDAY, JUNE 22, 2013

- 7:00 AM–6:00 PM REGISTRATION—Grand Ballroom Foyer
- 7:00 AM–6:00 PM SPEAKER READY ROOM OPEN—Coronado Room
- 7:30 AM–8:00 AM EDUCATION COURSE: COFFEE AND CONTINENTAL BREAKFAST—Salon B
- 8:00 AM–12:45 PM EDUCATION COURSE SESSION 1 (*Separate Registration Required*)—Salon B
- Principles of Teratology**
Organized by the Education Committee, Chairperson, Ali S. Faqi, MPI Research
- 8:00 AM–8:10 AM **Welcome**
Edward W. Carney, Teratology Society President
- 8:10 AM–8:40 AM **Narsingh Agnish Fellow Lecture**
James L. Schardein, Consultant
- 8:40 AM–8:45 AM **Course Overview**
Education Committee Chairperson, Ali S. Faqi, MPI Research
- 8:45 AM–9:30 AM **Timeline of Important Events for Embryo-Fetal Development**
John M. DeSesso, Exponent
- 9:30 AM–10:15 AM **Direct and Indirect Developmental Toxicity: Maternal, Placental, and Fetal Considerations** **CME**
John M. Rogers, US Environmental Protection Agency
- 10:15 AM–10:30 AM **Break**
- 10:30 AM–11:15 AM **Teratogenic Mechanisms, Pathways, and Processes** **CME**
Thomas B. Knudsen, US Environmental Protection Agency
- 11:15 AM–12:00 Noon **Contemporary Practices in Core Developmental Toxicity Assessments**
Ali S. Faqi, MPI Research
- 12:00 Noon–12:45 PM **Detecting Signals of Concern in the Human Population** **CME**
Christina D. Chambers, University of California San Diego

- 12:45 PM–1:45 PM LUNCH ON YOUR OWN
- 1:45 PM–5:30 PM EDUCATION COURSE SESSION 2 (*Separate Registration Required*)—Salon B
Advanced Technologies in Prenatal and Postnatal Screening and Diagnosis from Basic Science to Clinical Applications
Organized by the Education Committee, Chairperson, Ali S. Faqi, MPI Research
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| 1:45 PM–1:50 PM | Course Overview
<i>Education Committee Chairperson, Ali S. Faqi, MPI Research</i> |
| 1:50 PM–2:35 PM | Physics and Chemistry of Imaging: A Novice's Guide CME
<i>Michael A. Schellpfeffer, Medical College of Wisconsin</i> |
| 2:35 PM–3:20 PM | Designer Babies: Are We There Yet in IVF and Genetics? CME
<i>Elizabeth E. Puscheck, Wayne State University</i> |
| 3:20 PM–3:35 PM | Break |
| 3:35 PM–4:20 PM | Science and Application of Metabolic Disease Screening/Evaluation of Maternal Thyroid Function during Pregnancy and Screening for Congenital Hypothyroidism CME
<i>Sarah G. Obican, Columbia University</i> |
| 4:20 PM–5:05 PM | Biomarkers for Preeclampsia CME
<i>Sarosh Rana, Beth Israel Deaconess Medical Center</i> |
| 5:05 PM–5:30 PM | Discussion |
- 5:30 PM–6:30 PM CONSTITUTION AND BYLAWS COMMITTEE MEETING—Santa Rita
- 6:00 PM–8:00 PM STUDENT/POSTDOCTORAL FELLOW MIXER—Bill's Grill
- 6:30 PM–9:30 PM COUNCIL 1B MEETING AND COMMITTEE REPORTS/LEADERSHIP TRAINING—Executive Boardroom

SUNDAY, JUNE 23, 2013

- 7:00 AM–8:00 AM DINE WITH A TERATOLOGY AMBASSADOR (*Advanced Signup Required*)
- 7:00 AM–8:00 AM SCIENCE COMMITTEE MEETING—Executive Boardroom
- 7:00 AM–8:00 AM STUDENT AFFAIRS COMMITTEE MEETING—Santa Rita
- 7:00 AM–6:00 PM REGISTRATION—Grand Ballroom Foyer
- 7:00 AM–6:00 PM SPEAKER READY ROOM OPEN—Coronado Room
- 8:30 AM–8:45 AM PRESIDENT'S WELCOME—Salon B
Edward W. Carney, The Dow Chemical Company
- 8:45 AM–9:30 AM TS/OTIS JOINT JOSEF WARKANY LECTURE—Salon B
A Random Walk through Teratology (L1) CME
Chairperson: Edward W. Carney, The Dow Chemical Company
Lecturer: Robert J. Kavlock, US Environmental Protection Agency

9:30 AM–12:00 Noon STUDENT/POSTDOCTORAL FELLOW PLATFORM SESSION 1—Salon B

Organized by the Student Affairs Committee

Chairpersons: Jeff Charlap, WIL Research and Stephen B. Harris, Stephen B. Harris Group

Presenting author is underlined.

- 9:30 AM–9:45 AM **Introduction**
Student Affairs Committee Chairperson, Jeff Charlap, WIL Research
- 9:45 AM–10:00 AM **1 A Neurodevelopmental Human In Vitro 3-D Model for the Assessment of Gene/Environment Interactions**
Pamies D¹, Bressler J^{1,2}, Makri G³, Smirnova L¹, O'Driscoll C², Harris G¹, Song H³, Hartung T¹, Hogberg HT¹. ¹Center for Alternatives to Animal Testing, Johns Hopkins University, Bloomberg School of Public Health, Baltimore, MD, United States, ²Hugo Moser Institute at the Kennedy Krieger, Johns Hopkins University, Bloomberg School of Public Health, Baltimore, MD, United States, ³Institute for Cell Engineering, Department of Neurology, Johns Hopkins University, School of Medicine, Baltimore, MD, United States.
- 10:00 AM–10:15 AM **2 Dynamic Testicular Coculture Captures Key Processes of Male Reproductive Development Including Testosterone Production and Early Meiosis**
Wegner S, Harris S, Park J, Kim H, Pacheco S, Hong S, Faustman EM. University of Washington, Seattle, WA, United States.
- 10:15 AM–10:30 AM **3 Hydroxyurea Exposure during Mouse Organogenesis Perturbs the Embryonic Redox Potential**
Schlisser AE, Hales BF. McGill University, Montreal, QC, Canada.
- 10:30 AM–10:45 AM **4 Evaluation of a Redox-Sensitive Predictive Model of Mouse Embryonic Stem Cell Differentiation Using Multiple Differentiation Markers and Windows of Development**
Chandler KJ¹, Hansen JM², Knudsen TB¹, Hunter ES¹. ¹US Environmental Protection Agency, Research Triangle Park, NC, United States, ²Emory University School of Medicine, Atlanta, GA, United States.
- 10:45 AM–11:00 AM **Break**
- 11:00 AM–11:15 AM **5 Increased Nuclear Sphingoid Base-1-Phosphates and HDAC Inhibition after Fumonisin and FTY720-Treatment: The Link between Epigenomic Modifications and Neural Tube Defects?**
Gardner NM¹, Sachs AJ¹, Riley RT², Maddox JR¹, Gelineau-van Waes J¹. ¹Department of Pharmacology, Creighton University School of Medicine, Omaha, NE, United States, ²USDA-ARS, Toxicology and Mycotoxin Research Unit, R.B. Russell Research Center, Athens, GA, United States.
- 11:15 AM–11:30 AM **6 Correlative and Predictive Values of First-Trimester Urinary Phenol and Phthalate Concentrations from Two Boston-Based Prospective Birth Cohorts**
LaRocca JL^{1,3}, Binder AM², Carwile JL², Calafat AM⁴, Michels KB^{2,3}. ¹Harvard University Center for the Environment, Cambridge, MA, United States, ²Department of Epidemiology, Harvard School of Public Health, Boston, MA, United States, ³Obstetrics and Gynecology Epidemiology Center, Department of Obstetrics and Gynecology, Brigham and Women's Hospital, Boston, MA, United States, ⁴National Center for Environmental Health, Centers for Disease Control and Prevention, Atlanta, GA, United States.
- 11:30 AM–11:45 AM **7 Invasion of *Listeria monocytogenes* Strains in a Human Trophoblast Cell Line (BeWo)**
Wadhwa Desai R, Amosu M, Smith MA. University of Georgia, Athens, GA, United States.
- 11:45 AM–12:00 Noon **8 Epigenetic Regulation of MicroRNAs in Fetal Neural Stem Cells: Uncovering Novel Mechanisms of Ethanol Teratology**
Balaraman S, Doan R, Dindot S, Miranda R. Texas A&M Health Science Center, College of Medicine, Department of Neuroscience and Experimental Therapeutics, Bryan, TX, United States.

- 12:00 Noon–1:00 PM LUNCH ON YOUR OWN**
- 12:00 Noon–1:00 PM 2014 PROGRAM COMMITTEE MEETING—Executive Boardroom**
- 12:00 Noon–1:00 PM F. CLARKE FRASER AND SERVICE AWARDS COMMITTEE MEETING—Santa Rita**
- 1:00 PM–1:30 PM F. CLARKE FRASER NEW INVESTIGATOR AWARD—Salon B**
Diabetic Embryopathy: Unique Models for Revealing the Mechanism Underlying Structural Birth Defects (L2) **CME**
Chairperson: Ludmila Bakhireva, University of New Mexico
Lecturer: Peixin Yang, University of Maryland
- 1:30 PM–2:00 PM JAMES G. WILSON PUBLICATION AWARD—Salon B**
Bone Morphogenetic Proteins Regulate Hinge Point Formation during Neural Tube Closure by Dynamic Modulation of Apicobasal Polarity
Chairperson: L. David Wise, Merck Research Laboratories
Lecturer: Seema Agarwala, University of Texas
- 2:00 PM–3:00 PM TS/NBTS JOINT ELSEVIER DISTINGUISHED LECTURER—Salon A**
Placental Serotonin, Developmental Programming, and the Fetal Brain (L3) **CME**
Chairperson: Charles V. Vorhees, Cincinnati Children's Research Foundation
Lecturer: Pat Levitt, Southern California University
- 3:00 PM–6:30 PM TS/NBTS JOINT SYMPOSIUM—Salon A**
Prenatal Origins of Neuropsychiatric Disorders
Chairperson: Charles V. Vorhees, Cincinnati Children's Research Foundation
- 3:00 PM–3:45 PM S1 Prenatal Infection in Schizophrenia and Other Neuropsychiatric Disorders** **CME**
Alan S. Brown, New York Psychiatric Institute and Columbia University
- 3:45 PM–4:30 PM S2 Using Animal Models to Study Effects of Prenatal Infection on Brain Development and Behavior Relevant to Psychiatric Disorders** **CME**
Patricia Boksa, McGill University
- 4:30 PM–5:00 PM Break**
- 5:00 PM–5:45 PM S3 Prenatal Human Influenza Viral Infection and Brain Disorder in Mouse: Relevance for Genesis of Schizophrenia** **CME**
S. Hossein Fatemi, University of Minnesota
- 5:45 PM–6:30 PM S4 Imaging Early Childhood Brain Development: Implications for Schizophrenia** **CME**
John H. Gilmore, University of North Carolina, Chapel Hill
- 3:00 PM–6:30 PM ADVERSE OUTCOME PATHWAYS (AOPS) IN PREDICTIVE TOXICOLOGY SYMPOSIUM—Salon B**
Organized in conjunction with the Scientific Liaison Coalition
Chairpersons: Thomas B. Knudsen and Nisha S. Sipes, US Environmental Protection Agency
- 3:00 PM–3:45 PM S5 Adverse Outcome Pathways and Their Unifying Role in Developmental Toxicology** **CME**
Kevin Crofton, US Environmental Protection Agency
- 3:45 PM–4:30 PM S6 Key Events within AOPs Relevant to Developmental and Reproductive Toxicity**
George P. Daston, The Procter & Gamble Company

4:30 PM–5:00 PM	Break
5:00 PM–5:45 PM	S7 Adverse Outcome Pathways in Computational Toxicology CME <i>Nicole C. Kleinstreuer, US Environmental Protection Agency</i>
5:45 PM–6:30 PM	S8 Application of Adverse Outcome Pathway Approaches to Improve Reproductive and Developmental Toxicity Safety <i>Edward W. Carney, The Dow Chemical Company</i>
6:30 PM–8:30 PM	TS/NBTS WELCOME RECEPTION AND EXHIBITS OPEN—Kiva Ballroom
8:30 PM–9:30 PM	MEMBERSHIP COMMITTEE MEETING—Santa Rita

MONDAY, JUNE 24, 2013

7:00 AM–8:00 AM	BDRB EDITORIAL BOARD MEETING—Executive Boardroom
7:00 AM–8:00 AM	DINE WITH A TERATOLOGY AMBASSADOR (<i>Advanced Signup Required</i>)
7:00 AM–8:00 AM	FINANCE COMMITTEE MEETING—Santa Rita
7:00 AM–6:00 PM	REGISTRATION—Grand Ballroom Foyer
7:00 AM–6:00 PM	SPEAKER READY ROOM OPEN—Coronado Room
8:00 AM–8:30 AM	THALIDOMIDE ARCHIVE—Salon B
8:30 AM–9:00 AM	TS/OTIS JOINT ROBERT L. BRENT LECTURE: TERATOGEN UPDATE—Salon B Noninvasive Prenatal Diagnosis (NIPD) Using Cell-Free Fetal DNA (L7) CME <i>Chairperson: Edward W. Carney, The Dow Chemical Company</i> <i>Lecturer: Joe Leigh Simpson, March of Dimes Foundation</i>
9:00 AM–12:00 Noon	PLATFORM SESSION 2—Catalina Ballroom Molecular and Cellular Mechanisms of Abnormal Development <i>Chairpersons: Carolyn Kapron, Trent University and Louise M. Winn, Queen's University</i> Presenting author is <u>underlined</u> .
9:00 AM–9:15 AM	Introduction
9:15 AM–9:30 AM	9 Evaluation of Signaling Pathway Perturbation Using a Kinase Inhibitor Chemical Library in Mouse Embryonic Stem Cells ACDC Assay <i>Hunter S, Rosen M, Jeffay S, Hoopes M, Nichols H, Chandler K. ISTD, NHEERL, US EPA, Research Triangle Park, NC, United States.</i>
9:30 AM–9:45 AM	10 Inhibition of Glutathione Biosynthesis Alters Compartmental Redox Status and the Thiol Proteome in Organogenesis-Stage Rat Conceptuses <i>Hanasen JM¹, Harris C², Gomez RR², Schuster DZ², Sant KE², Pohl J³, Reed M³. ¹Emory University, Atlanta, GA, United States, ²University of Michigan, Ann Arbor, MI, United States, ³Center for Disease Control and Prevention, Atlanta, GA, United States.</i>
9:45 AM–10:00 AM	11 Valproic Acid Causes p53 Hyperacetylation and Inhibits Activation of the Autophagy Inhibitor mTOR in Murine Limb Buds <i>Paradis FH, Hales BF. McGill University, Montreal, QC, Canada.</i>
10:00 AM–10:15 AM	Break
10:15 AM–10:30 AM	12 A Proposed Mechanism for Thalidomide-Induced Limb Malformations <i>Scott WJ. Children's Hospital Research Foundation, Cincinnati, OH, United States.</i>

10:30 AM–10:45 AM	13	<p>A Comparative Assessment of Maternal Reproductive Parameters, Fetal Viability, and Hypertension with Surgical and Nonsurgical Models of Preeclampsia in the Sprague-Dawley Rat <i>Toot JD¹, Coder PS¹, Gleason TR¹, Edwards TR¹, Moehle RM¹, Loris SM¹, Reho JP². ¹WIL Research Laboratories, Ashland, OH, United States, ²University of Maryland, Baltimore, Department of Medicine, Division of Cardiology, Baltimore, MD, United States.</i></p>
10:45 AM–11:00 AM	14	<p>In Utero Caffeine Exposure Alters DNA Methylation Patterns and Gene Expression in Hearts <i>Fang X, Rivkees SA, Wendler CC. University of Florida, Gainesville, FL, United States.</i></p>
11:00 AM–11:15 AM	15	<p>The Splotch Allele Increases Sensitivity to NTDs Produced by High Doses of Arsenite and Cadmium Individually but Not to NTDs Caused by Lower Doses of Both in Combination: Implications for Mechanisms of Action <i>Machado AF, Huynh FK, Chung YE. Environmental and Occupational Health, California State University, Northridge, Northridge, CA, United States.</i></p>
11:15 AM–11:30 AM	16	<p>The Familial Nature of Renal Agenesis <i>Clark JC¹, Manak J¹, Darbro B¹, Kannan P², Holmes LB², Brophy PD¹. ¹University of Iowa, Iowa City, IA, United States, ²MassGeneral Hospital for Children, Boston, MA, United States.</i></p>
11:30 AM–11:45 AM	17	<p>Decreased Reproduction in Mice from Tap Water Exposure in a Facility Using QAC Disinfectants <i>Hrubec TC^{1,2}, Sugrue JE². ¹Via College of Osteopathic Medicine, Blacksburg, VA, United States, ²VA-MD Regional College of Veterinary Medicine, Virginia Tech, Blacksburg, VA, United States.</i></p>
11:45 AM–12:00 Noon		Discussion

9:00 AM–12:30 PM TS/OTIS JOINT ILSI HESI SYMPOSIUM—Salon B

Communication of Risk for Medication Use in Pregnancy and Lactation

Chairpersons: Christina D. Chambers, University of California, San Diego, Jane Stewart, AstraZeneca Pharmaceuticals, and Melissa S. Tassinari, US Food and Drug Administration

9:00 AM–9:05 AM	Introduction	<i>Melissa S. Tassinari, US Food and Drug Administration</i>
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Anticipating a Pregnancy and Lactation Label without Letters

9:05 AM–9:20 AM	S9	<p>Navigating Pregnancy and Lactation Labeling without Letters: A Review of the Proposed Changes to Product Labeling </p> <p><i>Melissa S. Tassinari, US Food and Drug Administration</i></p>
9:20 AM–9:35 AM	S10	<p>The Animal Data: Making it Clear and Relevant </p> <p><i>Melissa S. Tassinari, US Food and Drug Administration</i></p>
9:35 AM–9:50 AM	S11	<p>Anticipated Improvements to Human Data Content in the Proposed US FDA Pregnancy Label </p> <p><i>Cheryl S. Broussard, Centers for Disease Control and Prevention</i></p>
9:50 AM–10:00 AM		Questions for Speakers

Break

Where Do the Data Come From?

10:15 AM–10:30 AM	S12	<p>Maximizing the Value of the Nonclinical Data for Evaluation of Risk in Pregnancy and Lactation <i>Susan Bielmeier Laffan, GlaxoSmithKline Pharmaceuticals</i></p>
10:30 AM–10:45 AM	S13	<p>Data Collection Methods for Use of Medications in Pregnancy </p> <p><i>Melissa S. Tassinari, US Food and Drug Administration</i></p>
10:45 AM–11:00 AM	S14	<p>Electronic Health Records and Beyond: Exploring Innovative New Data Sources <i>Sara H. Riordan, Lifetech</i></p>

11:00 AM–11:10 AM Questions for Speakers

Communication of Reproductive Risk

11:10 AM–11:25 AM S15 **Using Animal and Human Data to Communicate Risk: Perspectives of a Clinician**
Lisa L. Mathis, Amgen

11:25 AM–11:40 AM S16 **Putting the Risk in Context: Communicating the Impact of the Underlying Disease Condition and Pharmacotherapy during Pregnancy** **CME**
Katherine L. Wisner, Northwestern University

11:40 AM–11:55 AM S17 **How Is Risk Perceived amongst Patients?** **CME**
Sarah G. Obican, Columbia University

11:55 AM–12:05 PM Questions for Speakers

12:05 PM–12:30 PM Panel Discussion

12:30 PM–1:30 PM LUNCH ON YOUR OWN

12:30 PM–1:30 PM PAST PRESIDENTS' AND HONOREES' LUNCHEON (*By Invitation Only*)—Santa Rita

1:30 PM–3:45 PM PLATFORM SESSION 3—Catalina Ballroom

Hazard Assessment, Risk Characterization, and Risk Management of Pre- and Postnatal Impacts on Development

Chairpersons: Linda G. Roberts, Chevron Energy Technology Company and Jason Stanko, National Institute of Environmental Health Sciences

Presenting author is underlined.

1:30 PM–1:45 PM Introduction

1:45 PM–2:00 PM 18 **Time Course for Onset and Recovery of Effects of a Novel Male Reproductive Toxicant: Implications for Apical Preclinical Study Designs**
Stewart J. AstraZeneca Pharmaceuticals, Macclesfield, United Kingdom.

2:00 PM–2:15 PM 19 **Developmental Immunotoxicity Testing for Hazard Identification**
Tonk ECM^{1,2}, Verhoef A¹, van Loveren H^{1,2}, Piersma AH^{1,3}. ¹RIVM, Bilthoven, Netherlands, ²Maastrich University, Maastricht, Netherlands, ³IRAS, Utrecht, Netherlands.

2:15 PM–2:30 PM 20 **Dose Response of *Listeria monocytogenes* Invasion and Fetal Mortality during Pregnancy**
Roulo RM, Fishburn JD, Smith MA. University of Georgia, Athens, GA, United States.

2:30 PM–2:45 PM 21 **Effects of Developmental PCB Exposure on Energy Metabolism in Mice from 3 Months to 12 Months of Age**
Curran CP, Brown A, Ashworth A, Branham J, Smith K, Earnheart A. Northern Kentucky University, Highland Heights, KY, United States.

2:45 PM–3:00 PM 22 **MicroPET/CT Imaging of [18F]-FEPPA in the Nonhuman Primate: A Potential Biomarker of Pathogenic Processes Associated with Anesthetic-Induced Neurotoxicity**
Slikker Jr. W¹, Zhang X¹, Paule MG¹, Newport GD¹, Liu F¹, Callicott R¹, Liu S¹, Berridge M^{2,3}, Apana SM^{2,3}, Wang C¹. ¹National Center for Toxicological Research, US Food and Drug Administration, Jefferson, AR, United States, ²3D Imaging, LLC, Little Rock, AR, United States, ³University of Arkansas for Medical Sciences, Little Rock, AR, United States.

- 3:00 PM–3:15 PM 23 **Preliminary Results from Prenatal Toxicity Study of Oxybenzone in Rats**
Inselman AL¹, Nakamura N¹, McIntyre B², Foster PMD², Harrouk W³, Hansen DK¹. ¹US FDA/NCTR, Jefferson, AR, United States, ²NTP/NIEHS, Research Triangle Park, NC, United States, ³US FDA/CDER, Silver Spring, MD, United States.
- 3:15 PM–3:30 PM 24 **Preventing Birth Defects: It Is About Time!**
Brent RL, Oakley GP. Alfred I. duPont Hospital for Children, Wilmington, DE, United States.
- 3:30 PM–3:45 PM Discussion

1:30 PM–6:00 PM TS/NBTS JOINT SYMPOSIUM—Salon A

Honoring the Legacy of Dr. Patricia M. Rodier

Chairpersons: Chris Stodgell, University of Rochester and

Charles V. Vorhees, Cincinnati Children's Research Foundation

- 1:30 PM–1:45 PM **Memories of Patricia M. Rodier**
Richard E. Butcher
- 1:45 PM–2:30 PM S18 **Manganese Neurotoxicity: From Worms to Neonates** CME
Michael Aschner, Vanderbilt University
- 2:30 PM–3:15 PM S19 **Cross-Species Comparisons of the Effects of Developmental Methylmercury Exposure: An Update of a Collaborative Project with Dr. Patty Rodier** CME
Thomas Burbacher, University of Washington
- 3:15 PM–4:00 PM S20 **Teratology of Autism: From Animal Models to Endophenotypes** CME
Chris J. Stodgell, University of Rochester
- 4:00 PM–4:30 PM Break
- 4:30 PM–5:15 PM S21 **Thalidomide, Moebius Sequence, and Misoprostol: Pieces to the Autism Puzzle** CME
Marilyn T. Miller, University of Illinois
- 5:15 PM–6:00 PM S22 **Syndromes and the Study of Autism** CME
Tara L. Wenger, Children's Hospital of Philadelphia

1:30 PM–6:00 PM TS/OTIS JOINT PREGNANCY REGISTRY WORKSHOP—Salon B

Pregnancy Registry Designs That Involve Multiple Drugs for Similar Indications: Advantages, Disadvantages, and Sustainable Funding Models

Chairpersons: Vincent T. Armenti, NTPR, Gift of Life Institute and

Lee S. Cohen, Massachusetts General Hospital

- 1:30 PM–1:40 PM **Introduction and Overview**
Lewis B. Holmes, MassGeneral Hospital for Children
- 1:40 PM–2:00 PM W1 **Pregnancy Registry Designs for Multiple Drugs for Similar Medications: North American AED (Antiepileptic Drug) Pregnancy Registry**
Lewis B. Holmes, MassGeneral Hospital for Children
- 2:00 PM–2:20 PM W2 **The National Pregnancy Registry for Atypical Antipsychotics: Effects of Fetal Exposure on Risk for Congenital Malformations and Maternal/Newborn Outcomes**
Lee S. Cohen, Massachusetts General Hospital
- 2:20 PM–2:40 PM W3 **Celebrating 20 Years: The Antiretroviral Pregnancy Registry**
Susan Sinclair Roberts, INC Research
- 2:40 PM–3:00 PM W4 **National Transplantation Pregnancy Registry**
Vincent T. Armenti, NTPR, Gift of Life Institute
- 3:00 PM–3:30 PM W5 **Is a Multisite Model for Collaboration across Investigators Feasible for a Single Multidrug Registry**
Gideon Koren, The Hospital For Sick Children

MONDAY

- 3:30 PM–4:00 PM W6 **How Should Classes of Medications Be Prioritized for Multidrug Approaches and How Can Generics Be Incorporated into These Efforts?**
Melissa S. Tassinari, US Food and Drug Administration
- 4:00 PM–4:15 PM **Break**
- 4:15 PM–4:45 PM W7 **Utility of Multidrug Disease-Based Pregnancy Registries to Inform Clinical Management Guidelines**
Cheryl S. Broussard, Centers for Disease Control and Prevention
- 4:45 PM–5:00 PM **Discussion**
- 5:00 PM–5:15 PM W8 **The Savella® (Milnacipran) Pregnancy Registry: Interim Analysis and Enrollment Challenges**
Hirsch DK¹, Sinclair Roberts S^{2,3}, Brown VD², Palmer R¹, McLean J², Leclair D¹. ¹Forest Research Institute, Jersey City, NJ, United States, ²INC Research, LLC, Division of Post-Approval and Strategic Services, Wilmington, NC, United States, ³University of North Carolina Wilmington, Wilmington, NC, United States.
- 5:15 PM–5:30 PM W9 **Trends in Postmarketing Commitments for Pregnancy Registries in the Five Years since FDAAA**
Covington D, McKain L. Pharmaceutical Product Development, Inc., Wilmington, NC, United States.
- 5:30 PM–5:45 PM W10 **Adverse Developmental Events Reported to US FDA in Association with Maternal Use of Topiramate in Pregnancy**
Tabacova S, Szarfman A. US Food and Drug Administration, Silver Spring, MD, United States.
- 5:45 PM–6:00 PM **Discussion**
- 6:00 PM–8:00 PM **TS/NBTS/OTIS JOINT POSTER SESSION 1 AND EXHIBITS OPEN—Kiva Ballroom**
Teratology Society Posters (Including the National Children’s Study Update): P1–P18
NBTS Posters: P1–P18
OTIS Posters: 1–6
- 8:00 PM–10:30 PM **TS/MARTA STUDENT CAREER EVENT—Upper Terrace**

TUESDAY, JUNE 25, 2013

- 6:30 AM–7:00 AM **SUNRISE MINI COURSE: COFFEE AND CONTINENTAL BREAKFAST—Salon B**
(For Sunrise Mini Course Registrants)
- 6:30 AM–5:00 PM **SPEAKER READY ROOM OPEN—Coronado Room**
- 7:00 AM–5:00 PM **REGISTRATION—Grand Ballroom Foyer**
- 7:00 AM–8:00 AM **DINE WITH A TERATOLOGY AMBASSADOR (Advanced Signup Required)**
- 7:00 AM–8:30 AM **SUNRISE MINI COURSE (Separate Registration Required)—Salon B**
Advanced Technologies in Genetics and Genomics: Applications to the Prevention of Birth Defects and the Communication of Risk
Organized by the Education Committee, Chairperson, Ali S. Faqi, MPI Research
- 7:00 AM–7:45 AM **Current Technologies in Genetic Testing** **CME**
Maximilian Muenke, National Human Genome Research Institute, NIH
- 7:45 AM–8:30 AM **Applications of Technologies and Communication of Risk** **CME**
Elaine M. Faustman, University of Washington

8:30 AM–9:15 AM SPECIAL LECTURE—Salon B**Clinical and Molecular Teratology***Chairperson: Elaine Z. Francis, Sandcastle Toxicology Associates**Lecturer: Michel Vekemans, Université Paris Descartes***9:15 AM–12:25 PM WILEY-BLACKWELL SYMPOSIUM—Salon B****Application of Imaging Technologies in Birth Defects Research and Clinical Practice***Chairpersons: Ali S. Faqi, MPI Research and Susan L. Makris, US Environmental Protection Agency**Endorsed by the Publications Committee***9:15 AM–9:50 AM S23 Visualizing Complex Cell Dynamics in the Living Embryo***Paul M. Kulesa, Stowers Institute for Medical Research***9:50 AM–10:25 AM S24 Imaging Modalities for High-Throughput Phenotyping of Structural Birth Defects in Mutagenized Fetal and Newborn Mice **CME*****Kimimasa Tobita, Children's Hospital of University of Pittsburgh Medical School***10:25 AM–10:40 AM Break****10:40 AM–11:15 AM S25 Ultrasound Imaging in Research and Clinical Medicine **CME*****Michael A. Schellpfeffer, Medical College of Wisconsin***11:15 AM–11:50 AM S26 Advances in Micro-CT Imaging for Preclinical Developmental Toxicology Evaluation***L. David Wise, Merck Research Labs***11:50 AM–12:25 PM S27 Brain Imaging Studies on Early Brain Development in Children with Prenatal Nicotine Exposure **CME*****Linda Chang, John A. Burns School of Medicine, University of Hawaii***12:25 PM–1:30 PM LUNCH ON YOUR OWN****12:30 PM–1:30 PM PUBLIC AFFAIRS COMMITTEE MEETING—Executive Boardroom****12:30 PM–1:30 PM PUBLICATIONS COMMITTEE MEETING—Santa Rita****1:30 PM–2:45 PM TS/ETS EXCHANGE LECTURE—Salon B****Myth or Merit: The Use of a Second Species in Developmental Toxicity Testing***Chairperson: Graham P. Bailey, Janssen Pharmaceutical N.V.***European Teratology Society****More Safe Drugs by Less In Vivo Testing? (L4)***Georg Schmitt, Hoffmann-LaRoche***Teratology Society****Screening Environmental Agents (L5)***Susan L. Makris, US Environmental Protection Agency*

2:45 PM–5:30 PM PLATFORM SESSION 4—Catalina Ballroom

***In Vitro*, Computational, and Alternative Methods and Models for Screening Developmental Toxicants**

Chairpersons: Susan Euling, US Environmental Protection Agency and Michael F. O'Hara, Covance Laboratories, Inc.

Presenting author is underlined.

- 2:45 PM–3:00 PM Introduction
- 3:00 PM–3:15 PM 25 **Identification of Pathways of Developmental Neurotoxicity by Metabolomics in a 3-D Organotypic Brain Cell Model Exposed to Lead Chloride**
Hogberg HT¹, Bouhifd M¹, Dao T¹, Harris G¹, Kleensang A¹, Nolan SJ¹, Odwin-DaCosta S¹, Pamies D¹, Smirnova L¹, van Vliet E², Welles H¹, Zhao L¹, Hartung T¹. ¹The Johns Hopkins University, Bloomberg School of Public Health, Center for Alternatives to Animal Testing, Baltimore, MD, United States, ²University of Barcelona, Fetal and Perinatal Medicine Research Group, August Pi i Sunyer Biomedical Research Institute, Hospital Clinic, Barcelona, Spain.
- 3:15 PM–3:30 PM 26 **Computational Embryology and Predictive Toxicology of Cleft Palate**
Sipes NS¹, Hutson MS², Baker NC¹, Knudsen TB¹. ¹US EPA/ORD/NCCT, Research Triangle Park, NC, United States, ²Departments of Physics and Astronomy and Biological Sciences, Vanderbilt University, Nashville, TN, United States.
- 3:30 PM–3:45 PM 27 **Effects of Perfluorinated Chemicals on Adipocyte Development**
Watkins AM, Wood CR, Lin MT, Abbott BD. US EPA, Research Triangle Park, NC, United States.
- 3:45 PM–4:00 PM Break
- 4:00 PM–4:15 PM 28 **The Use of Genetic Model Systems for Assessing Environmental Effects on Reproduction**
Kleinstreuer N¹, Knudsen T¹, Colaiacovo M², Allard P³. ¹NCCT, US EPA, Research Triangle Park, NC, United States, ²Harvard Medical School, Boston, MA, United States, ³UCLA, Los Angeles, CA, United States.
- 4:15 PM–4:30 PM 29 **Effects of Bulk- and Nano-Vitamin A in Postimplantation Rat Embryos Cultured *In Vitro***
Di Renzo F, Bacchetta R, Menegola E. Università degli Studi di Milano, Milano, Italy.
- 4:30 PM–4:45 PM 30 **Teratogenic Effects of Mixtures of Azole Fungicides Assessed by Using a New Dymorphogenic Method for Branchial Arch Defects Evaluation**
Menegola E, Di Renzo F. Università degli Studi di Milano, Milan, Italy.
- 4:45 PM–5:00 PM 31 **Triazole-Induced Gene Expression Changes in the Zebrafish Embryo**
Hermesen SAB^{1,2}, Pronk TE^{1,2}, van den Brandhof EJ¹, van der Ven LTM¹, Piersma AH^{1,3}. ¹RIVM, Bilthoven, Netherlands, ²MaastrichUniversity, Maastricht, Netherlands, ³IRAS, Utrecht, Netherlands.
- 5:00 PM–5:15 PM 32 **Interactive Effects of Methylmercury and Other Stressors: *Daphnia pulex* As an Alternative Model Organism for Early-Life Exposures**
Gohlke JM, Doke D. University of Alabama at Birmingham, Birmingham, AL, United States.
- 5:15 PM–5:30 PM Discussion

2:45 PM–5:30 PM TS/OTIS JOINT SYMPOSIUM—Salon B

Cancer and Pregnancy: Considerations regarding the Use of Chemotherapy

Chairpersons: Kembra Howdeshell and Michael Shelby, National Toxicology Program, NIEHS

- 2:45 PM–2:50 PM Introduction **CME**
Kembra Howdeshell, National Toxicology Program, NIEHS
- 2:50 PM–3:20 PM S28 **Prenatal Care for the Pregnant Cancer Patient** **CME**
Elyce H. Cardonick, Cooper Health System

- 3:20 PM–3:50 PM S29 **Detection and Administration of Systemic Therapies for Breast Cancer during Pregnancy** **CME**
Jennifer K. Litton, University of Texas MD Anderson Cancer Center
- 3:50 PM–4:05 PM **Break**
- 4:05 PM–4:35 PM S30 **Summary of National Toxicology Program Monograph on Developmental Effects of Cancer Chemotherapy Administered during Pregnancy** **CME**
Kembra Howdeshell, National Toxicology Program, NIEHS
- 4:35 PM–5:05 PM S31 **Oncofertility: Expanding the Parenthood Options for Life after Cancer** **CME**
Laxmi A. Kondapalli, University of Colorado, Anschutz Medical Campus
- 5:05 PM–5:30 PM **Discussion** **CME**

5:30 PM–7:30 PM **TS/OTIS JOINT POSTER SESSION 2 AND EXHIBITS OPEN—Kiva Ballroom**
Teratology Society Posters: P19–P44 and LB1–LB10
OTIS Posters: 1–6

WEDNESDAY, JUNE 26, 2013

- 6:30 AM–8:00 AM **TERATOLOGY SOCIETY 32ND ANNUAL VOLLEYBALL GAME—Udall Park**
- 7:00 AM–2:30 PM **REGISTRATION—Grand Ballroom Foyer**
- 7:00 AM–2:30 PM **SPEAKER READY ROOM OPEN—Coronado Room**
- 8:00 AM–8:45 AM **SPECIAL LECTURE—Salon B**
New Experimental Approaches for Exploring the Genetic/Epigenetic Landscape of Environmental Exposures
Chairperson: Edward W. Carney, Teratology Society President
Lecturer: Rick Woychik, National Institute of Environmental Health Science
- 8:45 AM–12:00 Noon **MARCH OF DIMES SYMPOSIUM—Salon B**
Advances in the Genomic Sciences towards Public Understanding and Predicting Developmental Defects
Chairpersons: Nicole C. Kleinstreuer, US Environmental Protection Agency and Peixin Yang, University of Maryland
- 8:45 AM–9:15 AM S32 **Genomic Analysis of Human Susceptibility to Neural Tube Defects** **CME**
Richard H. Finnell, University of Texas, Austin
- 9:15 AM–9:45 AM S33 **Epigenomic Signatures of Craniofacial Development** **CME**
M. Michele Pisano, University of Louisville Birth Defects Center
- 9:45 AM–10:30 AM **Warkany Tea**
- 10:30 AM–11:00 AM S34 **Two Distinct Epigenetic Pathways: DNA Hypermethylation and Histone Acetylation in Maternal Diabetes-Induced Neural Tube Defects** **CME**
Peixin Yang, University of Maryland
- 11:00 AM–11:30 AM S35 **A Transcriptomic Comparison between the Neural and Cardiac Embryonic Stem Cell Tests (ESTn and ESTc)** **CME**
A.H. Piersma, National Institute for Public Health and the Environment (RIVM)

- 11:30 AM–12:00 Noon S36 **A Metabolomics Based Assay to Rapidly Predict Mammalian Developmental Toxicity Using Human Pluripotent Stem Cells (hPSCs)**
Alan M. Smith, Stemina Biomarker Discovery

8:45 AM–12:00 Noon **PLATFORM SESSION 5—Catalina Ballroom**

Clinical Teratology and Epidemiology

Chairpersons: Vincent T. Armenti, NTPR, Gift of Life Institute and Marilyn T. Miller, University of Illinois

Presenting author is underlined.

- 8:45 AM–9:00 AM **Introduction**
- 9:00 AM–9:15 AM 33 **Telemedicine for Genetic and Neurologic Subspecialty Evaluations in a Neonatal Intensive Care Unit**
Wenger TL^{1,2}, Abend N³, Deardorff MA¹, Taub K³, Swarr DT^{1,4}, Gerdes J⁴.
¹Division of Genetics, Children's Hospital of Philadelphia, Philadelphia, PA, United States, ²Section of Clinical Informatics, Division of General Pediatrics, Children's Hospital of Philadelphia, Philadelphia, PA, United States, ³Division of Neurology, Children's Hospital of Philadelphia, Philadelphia, PA, United States, ⁴Division of Neonatology, Children's Hospital of Philadelphia, Philadelphia, PA, United States.
- 9:15 AM–9:30 AM 34 **Hypospadias and Genes Related to Genital Tubercle and Early Urethral Development**
Carmichael SL¹, Ma C¹, Choudhry S², Lammer EJ³, Witte JS², Shaw GM¹.
¹Stanford University, Stanford, CA, United States, ²University of California, San Francisco, San Francisco, CA, United States, ³Children's Hospital Oakland Research Institute, Oakland, CA, United States.
- 9:30 AM–9:45 AM 35 **Late-Detected Critical Congenital Heart Disease among US Newborns: Estimating the Potential Impact of Universal Screening**
Ailes E^{1,2}, Peterson C¹, Riehle-Colarusso T¹, Oster ME^{1,3}, Olney RS¹, Cassell CH¹, Fixler DE⁴, Carmichael SL⁵, Shaw GM⁵, Gilboa SM¹.
¹National Center on Birth Defects and Developmental Disabilities, CDC, Atlanta, GA, United States, ²Epidemic Intelligence Service, CDC, Atlanta, GA, United States, ³Sibley Heart Center, Children's Healthcare of Atlanta, Emory University, Atlanta, GA, United States, ⁴University of Texas Southwestern Medical Center, Dallas, TX, United States, ⁵Department of Pediatrics, Division of Neonatal and Developmental Medicine, Stanford University Medical School, Palo Alto, CA, United States.
- 9:45 AM–10:30 AM **Warkany Tea**
- 10:30 AM–10:45 AM 36 **Vascular Disruption Limb Defects: Correlation with Advanced Maternal Age?**
Nasri HN¹, Macklin EM², Holmes LH³. ¹Simmons College, Boston, MA, United States, ²Department of Biostatistics, MassGeneral Hospital for Children, Boston, MA, United States, ³Massachusetts General Hospital and Medical Genetics, MassGeneral Hospital for Children, Boston, MA, United States.
- 10:45 AM–11:00 AM 37 **Association of Maternal Stressors and Social Support with Risks of Birth Defects**
Carmichael SL¹, Ma C¹, Tinker S², Rasmussen S², Shaw GM¹. ¹Stanford University, Stanford, CA, United States, ²Centers for Disease Control and Prevention, Atlanta, GA, United States.
- 11:00 AM–11:15 AM 38 **Risk Factors for Preterm Birth during Heat Waves: Trends in Urban and Rural Settings in the Deep South**
Gohlke JM¹, Kent ST¹, McClure LA¹, Smith TT², Zaitchik BF². ¹University of Alabama at Birmingham, Birmingham, AL, United States, ²Johns Hopkins University, Baltimore, MD, United States.
- 39 **Withdrawn**

- 11:15 AM–11:30 AM 40 **Validity of Maternal Alcohol Screening Questionnaires vs. Ethanol Biomarker**
Bakhireva LN, Gutierrez H, Stephens E, Goff C, Savich RD, Savage DD, Leeman L, Rayburn WF. University of New Mexico Health Sciences Center, Albuquerque, NM, United States.
- 11:45 AM–12:00 Noon 41 **An Ongoing Register Study on Socioeconomic Variables in Adults with Fetal Alcohol Syndrome**
Stromland K¹, Rangmar J², Dahlgren Sandberg A^{2,3}, Aronson M^{2,4}, Fahlke C^{2,5}. ¹Department of Ophthalmology, Institute of Neuroscience and Physiology, Gothenburg University, Gothenburg, Sweden, ²Department of Psychology, Institute of Neuroscience and Physiology, Gothenburg University, Gothenburg, Sweden, ³Department of Psychology, Institute of Neuroscience and Physiology, Gothenburg University, Gothenburg, Sweden, ⁴Department of Psychology, Institute of Neuroscience and Physiology, Gothenburg University, Gothenburg, Sweden, ⁵Department of Psychology, Institute of Neuroscience and Physiology, Gothenburg University, Gothenburg, Sweden.
- 9:45 AM–10:30 AM **WARKANY TEA—Grand Ballroom Foyer**
- 12:00 Noon–1:00 PM **LUNCH ON YOUR OWN**
- 12:00 Noon–1:00 PM **EDUCATION COMMITTEE MEETING—Santa Rita**
- 1:00 PM–4:00 PM **PUBLIC AFFAIRS COMMITTEE SYMPOSIUM—Salon B**
Diabetes and Pregnancy
Chairpersons: Gloria D. Jahnke, National Institute of Environmental Health Sciences and Asher Ornoy, Israeli Teratology Information Service, Israel Ministry of Health and Hebrew University
Endorsed by the Society for Maternal-Fetal Medicine
- 1:00 PM–1:15 PM S37 **Obesity and Diet As Emerging Causes for Diabetes Mellitus in Pregnancy** **CME**
Richard K. Miller, University of Rochester
- 1:15 PM–1:45 PM S38 **Outcomes for Complications of Pregestational Diabetes** **CME**
E. Albert Reece, University of Maryland Medical School
- 1:45 PM–2:15 PM S39 **Neurodevelopmental Outcome of Children Born to Women with Pregestational and Gestational Diabetes** **CME**
Asher Ornoy, Israeli Teratology Information Service, Israel Ministry of Health and Hebrew University
- 2:15 PM–2:30 PM **Break**
- 2:30 PM–3:00 PM S40 **Genetic and Epigenetic Effects of Diabetes in Pregnancy** **CME**
Gabriela Pavlinkova, Institute of Biotechnology, Czech Republic
- 3:00 PM–3:30 PM S41 **Molecular Basis of Birth Defects in Diabetic Pregnancies: Implications for Developmental Programming of Metabolic Syndrome** **CME**
Claudia Kappen, Louisiana State University
- 3:30 PM–3:45 PM S42 **How Far Are We from Prevention of Diabetes and Its Complications?** **CME**
E. Albert Reece, University of Maryland Medical School
- 3:45 PM–4:00 PM **Discussion** **CME**
- 4:15 PM–5:45 PM **BUSINESS MEETING—Salon B**

6:30 PM–7:30 PM BANQUET RECEPTION—Kiva Patio

7:30 PM–11:00 PM BANQUET—Kiva Ballroom
Travel Awards
James C. Bradford Memorial Student Poster Awards
Wilson Presentation Awards
Marie Taubeneck Award
Distinguished Service Award

THURSDAY, JUNE 27, 2013

7:00 AM–10:00 AM COUNCIL 2 MEETING—Executive Boardroom