

Food and Drug Administration

State of the Science on Assessing Developmental Neurotoxicity (DNT) Using New Approach Methods (NAMs)

Harvey W. Wiley Federal Building
Auditorium

College Park, Maryland USA

November 14-15, 2023

Agenda

Day 1: Tuesday, November 14, 2023

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| 7:30 am – 8:30 am | Registration and Continental Breakfast |
| 8:30 am – 8:35 am | Welcome and Workshop Logistics
<i>Omari Bandele</i>
<i>Senior Advisor for Toxicology,</i>
<i>US FDA, Center for Food Safety and Applied Nutrition (CFSAN)</i>
<i>College Park, Maryland USA</i> |
| 8:35 am – 8:45 am | Introduction
<i>Steven Musser</i>
<i>Deputy Center Director for Scientific Operations</i>
<i>US FDA, Center for Food Safety and Applied Nutrition (CFSAN)</i>
<i>College Park, Maryland USA</i> |
| 8:45 am – 9:10 am | Opening Plenary
Two Decades Learning on the Road to Non-Animal DNT
<i>Thomas Hartung</i>
<i>Johns Hopkins University</i>
<i>Center of Alternatives to Animal Testing (CAAT)</i>
<i>Baltimore, Maryland USA</i> |

Session 1: Evaluation of the Developmental Neurotoxicity Potential of Chemicals Using In Vitro Model Systems

- 9:10 am – 9:15 am Introduction
- 9:15 am – 9:40 am An Integrated Testing Strategy to Screen Chemicals for Developmental Neurotoxicity
Helena Hogberg
NIH, National Institute of Environmental Health Sciences (NIEHS)
Durham, North Carolina USA
- 9:40 am – 10:05 am Computational Approaches to Evaluating Developmental Neurotoxicity (DNT) New Approach Methods (NAMs)
Kelly Carstens
US Environmental Protection Agency (EPA)
Durham, North Carolina USA
- 10:05 am – 10:30 am Advanced 3D Brain Microphysiological System (MPS) for Complex DNT Endpoints
Lena Smirnova
Johns Hopkins University
Center of Alternatives to Animal Testing (CAAT)
Baltimore, Maryland USA
- 10:30 am – 10:55 am Functional Brain Region-Specific Neural Organotypic Models for Compound Screening
Marc Ferrer
NIH, National Center for Advancing Translational Sciences (NCATS)
Bethesda, Maryland USA
- 10:55 am – 11:15 am Panel Discussion
- 11:15 am – 11:30 am Break

Session 2: Go Fish! Non-Mammalian Animal Models for the Evaluation of Developmental Neurotoxicity

- 11:30 am – 11:35 am Introduction
- 11:35 am – 12:00 pm Scientific Rationale and Opportunities to Use Integrated Models for DNT Assessments

*Robyn Tanguay
Oregon State University
Corvallis, Oregon USA*

12:00 pm – 12:25 pm Scaling Up Sociality: High-Throughput and Computational Assessment of Social Behavior in Zebrafish

*Yijie Geng
University of Washington
Seattle, Washington USA*

12:25 pm – 12:35 pm Panel Discussion

12:35 pm – 2:00 pm Lunch

Session 3: Adverse Outcome Pathways (AOPs) to Identify Key Neurodevelopmental Processes and Biomarkers

2:00 pm – 2:05 pm Introduction

2:05 pm – 2:30 pm The OECD Adverse Outcome Pathways (AOP) Program Supports Integrated Approaches to Testing and Assessment (IATA) and Biomarkers Development for DNT through the Contextualization of Mechanistic Information

*Magdalini Sachana
Organization for Economic Cooperation and Development (OECD)
Paris, France*

2:30 pm – 2:55 pm Progress in Linking DNT In Vitro Battery Endpoints to Adverse Outcome Pathways

*Timothy Shafer
US Environmental Protection Agency (EPA)
Durham, North Carolina USA*

2:55 pm – 3:20 pm Novel Molecular Initiating and Key Events by Linking DNT to Endocrine Disruption and Epigenetic Changes

*Joëlle Rüegg
Uppsala University
Uppsala, Sweden*

- 3:20 pm – 3:40 pm Panel Discussion
- 3:40 pm – 3:45 pm Closing Remarks/Adjourn
Omari Bandele
Senior Advisor for Toxicology
US FDA, Center for Food Safety and Applied Nutrition (CFSAN)
College Park, Maryland USA
- 4:00 pm – 5:30 pm Reception (Crowne Plaza College Park, 6400 Ivy Lane, Greenbelt,
Maryland 20770)

Day 2: Wednesday, November 15, 2023

- 7:30 am – 8:30 am Registration and Continental Breakfast
- 8:30 am – 8:35 am Welcome and Workshop Logistics
Omari Bandele
Senior Advisor for Toxicology
US FDA, Center for Food Safety and Applied Nutrition (CFSAN)
College Park, Maryland USA
- 8:35 am – 8:45 am Introduction
Suzanne Fitzpatrick
Senior Advisor for Toxicology
US FDA, Center for Food Safety and Applied Nutrition (CFSAN)
College Park, Maryland USA

Session 4: Assay Gaps in the Developmental Neurotoxicity Alternative Testing Battery for Key Neurodevelopmental Processes

- 8:45 am – 8:50 am Introduction
- 8:50 am – 9:30 am Identifying and Closing the Gaps of the DNT In Vitro Battery:
Towards a Reduction of Uncertainty
Ellen Fritsche
IUF - Leibniz Research Institute for Environmental Medicine
Düsseldorf, Germany
- 9:30 am – 9:55 am Sex Differences and Other Missing Factors for In Vitro DNT
Maren Schenke

*Johns Hopkins University
Center of Alternatives to Animal Testing (CAAT)
Baltimore, Maryland USA*

9:55 am – 10:10 am Panel Discussion

10:10 am – 10:40 am Break

**Session 5: Toward the Regulatory Use of DNT NAMs for Chemical Risk Assessment
(Part 1)**

10:40 am – 10:45 am Introduction

10:45 am – 11:10 am Establishing Confidence in DNT-NAMs for Regulatory Use
*Timothy Shafer
US Environmental Protection Agency (EPA)
Durham, North Carolina USA*

11:10 am – 11:35 am An Integrated Testing Strategy to Screen Chemicals for
Developmental Neurotoxicity
*Sue Marty
DOW Chemical Company
Midland, Michigan USA*

11:35 am – 12:00 pm Single Chemical Risk Assessment Integrated Approaches to
Testing and Assessment (IATA) Case Studies Using NAMs for
DNT
*Iris Mangas
European Food Safety Authority (EFSA)
Parma, Italy*

12:00 pm – 12:25 pm Panel Discussion

12:25 pm – 1:25 pm Lunch

**Session 6: Are we there yet? Toward the Regulatory Use of DNT NAMs for Chemical Risk
Assessment (Part 2)**

1:25 pm – 1:30 pm Introduction

- 1:30 pm – 1:55 pm Regulatory Application of the DNT Battery for Pesticide Evaluation
Monique Perron
US Environmental Protection Agency (EPA)
Washington, District of Columbia USA
- 1:55 pm – 2:20 pm The EU Regulatory Landscape and the EFSA Prospective Plan for the Regulatory Implementation of the DNT In Vitro Battery (IVB)
Andrea Terron
European Food Safety Authority (EFSA)
Parma, Italy
- 2:20 pm – 2:45 pm Leveraging NAMs to Enhance Developmental Neurotoxicity
John Talpos
US FDA, National Center for Toxicological Research (NCTR)
Jefferson, Arkansas USA
- 2:45 pm – 3:10 pm Availability of DNT IVB Methods as a Prerequisite for Regulatory Acceptance in Europe: A Start-Up Perspective
Ellen Fritsche
DNTOX
Düsseldorf, Germany
- 3:10 pm – 3:35 pm Panel Discussion
- 3:35 pm – 3:40 pm Closing Remarks/Adjourn
Omari Bandele
Senior Advisor for Toxicology
US FDA, Center for Food Safety and Applied Nutrition (CFSAN)
College Park, Maryland USA