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HESI DART Workshop: Interpretation of Developmental and Reproductive Toxicity (DART) in Regulatory Contexts and Frameworks

October 25 – 26, 2022
HESI Offices
Washington, DC, USA

Workshop Goal: The purpose of this workshop is to provide training and bolster the ability for investigators across disciplines to interpret DART data with confidence in the context of regulatory frameworks and processes. Since DART is a highly specialized sub-field of toxicology and biological science, experts with fluency in interpretation of DART data rely on years of graduate, post-graduate, and applied professional experience to discern adverse effects of substance exposure in developing organisms, including infants and children. This is an information sharing workshop to discuss and come to a consensus on recommendations/key principles on how to improve interpretation of nonclinical DART safety data in relationship to adverse outcomes. The intended audience for this workshop includes academic scientists, clinicians, individuals from international regulatory bodies and industry who directly or indirectly interpret DART data.

Day 1 – Tuesday October 25, 2022		
Session 1: Introduction to DART/Setting the Stage 9:00am – 12:00pm Eastern		
9:00am – 9:05am	**Opening Remarks**	**April Kluever (OMB)**
9:05am – 10:00am	**Interpretation of DART Data in Regulatory Contexts and Frameworks** -Weight of evidence -Integrated assessment	**Maia Green (Hurley Consulting) & Mary Ellen McNerney (US FDA)**
10:00am – 11:00am	**Debatable DART-adverse outcomes**	**Alan Hoberman (CRL)**
11:00am – 12:00am	**Interpretation of adversity from pathology perspective**	**Wendy Halpern (Genentech)**
12:00pm – 1:00pm	***Lunch Break***	
Session 2: Breakout Groups (Part 1) 1:30pm – 4:30pm Eastern		
1:00pm– 1:15pm	Breakout group instructions	**Maia Green (Hurley Consulting), April Kluever (OMB)**
1:15pm – 4:00pm	Breakout group discussions • Discuss 3-4 examples of fetal & repro data for the interpretation of adversity • Output: bullet points of consensus points for Day 2 report back	All

4:00pm – 4:30pm	Breakout groups wrap-up and prepare for report back	All
4:30pm	**Adjourn**	
Day 2 – Wednesday October 26, 2022		
Session 3: Breakout Group (Part 2) 8:30am – 11:30am Eastern		
8:30 am – 8:35	**Welcome back**	
8:35 am – 11:30am	**Case study presentation (Developmental Neurotoxicity): Use of NAMs for Weight of Evidence to Support Regulatory Decision-Making** Breakout group discussions	**Tim Shafer (US EPA)** All
Session 4: Wrap-Up/Brainstorming 11:30am – 12:00pm Eastern		
11:30am – 12:00pm	**Wrap-up/Brainstorming of Lessons Learned** - Consensus - Divergence - Pain points - Recommendations	**Maia Green (Hurley Consulting), April Kleuver (OMB)**
12:00pm	**Adjourn**	

Workshop output: White paper/editorial/short communication