

**Title:**

Advancing Developmental Neurotoxicity Assessment Using New Approach Methodologies in the European H2020 ONTOX Project

**Speaker:**

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**Abstract:**

Current regulatory developmental neurotoxicity (DNT) guidelines rely on *in vivo* tests with scientific, practical, and ethical limitations, necessitating more reliable and efficient human-based new approach methodologies (NAMs). The ONTOX project develops such NAMs by integrating *in vitro* and *in silico* approaches to predict DNT effects. A central component is an AI-driven ontology: a framework qualitatively and quantitatively integrating state-of-the-art DNT knowledge. The ontology combines a physiological map of human brain development and an adverse outcome pathway network linking prenatal chemical exposure to decreased cognition in children. The ontology is further integrated with a human-based *in vitro* battery employing 2D and 3D models. The *in vitro* assays are rigorously characterized and functionally mapped to human neurodevelopmental disorders to enhance their regulatory acceptance. This approach aligns with next-generation risk assessment principles, promoting human-relevant, animal-free DNT evaluation of chemicals.