2023 Developmental Toxicity NAMs Scoping Review Update

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In late 2020, ACC LRI initiated a scoping review to determine the state of the science or Developmental Toxicity New Approach Methodologies (DevTox NAMs) to determine if there are research areas of particular interest for the LRI, or if there are noticeable gaps that could be considered. For efficiency of available resources and time, ICF, a contractor to the ACC LRI, developed a scoping report as it is a limited systematic review, still completed in a systematic and comprehensive manner but is not designed nor guaranteed to find every article or publication on a topic. Rather, the process is designed to find a representative sample of the landscape of the topic. Three total reviews have been completed, resulting in over 300 references having been identified.

In 2023, under contract to the ACC LRI, ICF will conduct a literature update to (*i*) identify recently published reporting concerning the previously investigated developmental toxicity topics of interest and (*ii*) highlight research concerning the five new developmental toxicity topics of interest. The new developmental toxicity topics of interest were determined based on current government and industry research interest. These include: developmental neurotoxicity and respective assay/test batteries; embryonic stem cells; thyroid (general) and respective assay/test batteries; zebrafish and respective assay/test batteries; and induced pluripotent stem cells (iPSCs) utilized within developmental toxicity assays.

The overall goal of the scoping report is to identify what set of DevTox NAMs could be explored or researched further to be able to generate comparative data on sensitivity, specificity, and potency to establish sufficient similarity to support to use of one assay over another, use of assays interchangeably, or select an optimal set of DevTox NAM assays for a specific decision context.

The scoping review results to date are available to the public through an <u>online, interactive Tableau visual</u> and a <u>2022 peer-reviewed publication</u> detailing methods, results, and areas of future scientific interest.

Implications: The scoping report will be utilized to identify systems that currently have available assays and/or areas of research that need more development. This knowledge will help determine, by tissue/system, if all critical phases of development are adequately reported in peer-reviewed and publicly available reports.

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