

Supplementary Table 2 | Round 1 Questions to the NEWG

Theme	Question
At what point following approval should human neurodevelopmental outcomes be assessed?	<ul style="list-style-type: none"> • Should child neurodevelopment be investigated routinely for all medications following approval for use in humans? • Are there certain medication exposures which should be prioritised for neurodevelopmental investigation?
Barriers to neurodevelopmental outcome research	<ul style="list-style-type: none"> • Are pre-clinical (animal) study results predictive of human neurodevelopmental outcomes • Are there any barriers to researching neurodevelopmental outcomes in children exposed in the womb?
Core Outcomes	<ul style="list-style-type: none"> • Based on your informed professional opinion, which aspects of neurodevelopment can be altered by prenatal exposures (chemical, environmental or medicinal)? • Can a single score or single aspect of neurodevelopment be used to summarize neurodevelopmental functioning in all other areas? • What areas of neurodevelopment should be investigated before any conclusion can be made regarding risk or safety for a specific medication (e.g. by regulators, prescribers)? • What type(s) of investigations into neurodevelopment should be completed before conclusions can be made regarding either risk or safety for a specific medication?
Optimisation of Measurement	<ul style="list-style-type: none"> • What is the optimal way to measure neurodevelopment in a group of children exposed in utero? • At what age should the investigation of neurodevelopmental outcomes start? • At what age should the investigation of neurodevelopmental outcomes in exposed cohorts end? • At what age interval should longitudinal follow-up studies assess neurodevelopment? • Should the interval of assessment be different for exposures with early deviations in developmental trajectories versus those where development was similar to control children in infancy? • In your informed professional opinion, what variables are important to adjust for when investigating the impact of a given exposure? • In your informed professional opinion, what details about the exposure are important to record and consider? • We want to understand the optimal design features for the investigation of an exposure on child neurodevelopment. Please describe the ways that the methodology could be optimized in the following areas: Participant selection, Control/comparator, Exposure data, Measurement, Confounding optimization, Attrition, Other important design.
Interpretation	<ul style="list-style-type: none"> • What is good practice in the interpretations and reporting of outcomes? • How do we best convey the results from measures (e.g. questionnaires, psychometrics) which score on a continuous measurement? • How would you best communicate mean differences in infant/child outcomes in a way that is meaningful?
Other	<ul style="list-style-type: none"> • Is there any other topic in relation to neurodevelopmental outcomes which you would like to include in these discussions?