



Call for manuscript submission for *Special Issue* of

**Risk-Benefit Considerations and Drug Safety Processes for
Therapeutics Used in the Para-Natal Interval**

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There are three categories of therapeutics that present a compelling need for research and development. These therapeutics are used in the care of the obstetrical patient, her fetus, the neonate and child. We call for manuscript submission in the following areas but not limited to:

1. There are medications approved for treatment of several diseases that may be required during gestation. Concurrent maternal illnesses such as rheumatologic diseases, inflammatory bowel diseases, neuropsychiatric diseases necessitate unapproved administration of drugs to women while pregnant which have never been evaluated for pharmacokinetics or pharmacodynamics during pregnancy. The fetal impact of these specialized therapeutics as well as other generally prescribed and over-the-counter drugs all merit a thorough understanding in terms of potential adverse or beneficial effects on the fetus *in utero* and across the infant's later lifespan.
2. There are therapeutics that are specifically required to treat obstetrical conditions such as preterm labor, preeclampsia/chronic hypertension, diabetes/gestational diabetes, etc. These necessary obstetrical therapeutics have more background data regarding potential fetal effects. For some of these drugs such as magnesium sulfate, it is convincingly known to have a neuroprotective effect for the fetus when it is used to treat an obstetrical condition such as preterm labor. Due to accrual of clinical data, a thorough understanding of the benefit-risk profile for these drugs will be more readily attainable than that for the other categories of drugs being summarized herein.
3. New therapeutics to treat developmentally relevant disorders of the child/infant/fetus such as rare diseases/inherited genetic disorders is becoming available. These DNA/RNA, protein, or small molecule therapies to address specific genetic disorders might be effective and safe when given to children of a few years of age, neonates or even antenatally. Each of these developmental intervals will require its own set of efficacy and safety assessments. In order to advance these novel therapies into ultimate clinical practice, risk-benefit assessments and drug safety processes will need to be developed that incorporate a broad spectrum of maternal, *in utero* and post-natal infant outcomes.

We need to develop strategies to assess safety for the spectrum of potential new therapeutics that may be able to effectively modify the course of diseases that currently cannot be met. Numerous rare diseases that result from genomic and epigenetic causes express themselves in early developmental intervals. It is plausible to anticipate that any class of therapeutics to address these diseases will either require treatment administration during childhood, the neonatal interval, or antenatally to the fetus, early conceptus or pre-implantation embryo. In the recent past, unauthorized misuse of CRISPR technology

illustrated the necessity of transparency during research, development, and ultimate implementation of such therapeutic tools. Relevant considerations will necessarily include a comprehensive range of scientific, medical, regulatory, ethical, legal, political, and social factors.

We welcome original research papers, reviews and commentary articles on previously published papers in the literature.

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The manuscript can be submitted through online at
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Submission Deadlines:

Authors must return the finalized version of any submitted paper to the editorial office by **December 30, 2021** unless there has been editorial office approval for final submission by some later date.