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Call for manuscript submission for Special Issue (2019-01) 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/inherit 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 either
any class of therapeutics to address these diseases will require treatment administration
during childhood, the neonatal interval, or antenatally to the fetus, early conceptus or pre-
implantation embryo. Recently unauthorized misuse of CRISPR technology illustrates 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, legal, political, and social factors.

We welcome original research papers, reviews and commentary articles on previously published papers in the literature. There is no article-processing charge (APC) for the papers submitted to this Special Issue.

The submission of the manuscript can be divided into two steps, the first step is to submit a title and abstract (no more than 400 words), and then a full manuscript can be submitted later, through manuscript submission online at https://www.gcatresearch.com/manuscript-submission/.

Submission Deadlines:
April 30, 2019, for abstract
July 30, 2019, for full paper