

21<sup>st</sup> Annual Congress on

# NEONATOLOGY & PEDIATRICS

May 30-31, 2018 Osaka, Japan



## *Luana Pesco Koplowitz*

*Duck Flats Pharma, USA*

### **Drug-induced cardiac abnormalities in premature infants and neonates**

The cardiac safety research consortium (CSRC) is a transparent, public-private partnership that was established in 2005 as a critical path program and formalized in 2006 under a memorandum of understanding between the United States Food and Drug Administration, and Duke University. Our continuing goal is to advance paradigms for more efficient regulatory science related to the cardiovascular safety of new therapeutics, both in the United States and globally, particularly where such safety questions add burden to innovative research and development. This presentation is a summary of a white paper that provided a summary of discussions by a cardiovascular committee cosponsored by the CSRC and the US Food and Drug Administration (FDA) that initially met in December 2014 and periodically convened at FDA's White Oak headquarters from March 2015 to September 2016. The committee focused on the lack of information concerning the cardiac effects of medications in the premature infant and neonate population compared with that of the older pediatric and adult populations. Key objectives of this presentation are as follows: Provide an overview of human developmental cardiac electrophysiology, as well as the electrophysiology of premature infants and neonates, summarize all published juvenile animal models relevant to drug-induced cardiac toxicity, provide a consolidated source for all reported drug-induced cardiac toxicities by therapeutic area as a resource for neonatologists, present drugs that have a known cardiac effect in an adult population, but no reported toxicity in the premature infant and neonate populations and summarize what is not currently known about drug-induced cardiac toxicity in premature infants and neonates and what could be done to address this lack of knowledge. This presentation presents the views of the authors and should not be construed to represent the views or policies of the FDA or Health Canada.

### **Biography**

Luana Pesco Koplowitz, MD, PhD, FCP, FFPM is working as President and Chief Medical & Scientific Officer in DUCK FLATS PHARMA, LLC. She is extending her valuable service as a President and Chief Medical & Scientific Officer has been a recipient of many award and grants. Her research experience includes various programs, contributions and participation in different countries for diverse fields of study. Her research interests reflect in her wide range of publications in various national and International journals.

[lpk@dfpharma.com](mailto:lpk@dfpharma.com)

### **Notes:**