

# Toxicology and Clinical Pharmacology

## & Generic Drugs and Biosimilars

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#### Improving compliance with EMA and FDA pediatric regulations by improving the efficiency of pediatric drug development

While the list of unmet needs in child-appropriate drugs remains long, so does the list of R&D challenges, including recruitment of patients, availability of experienced investigators, high development costs, and increasingly complex regulatory requirements. Prioritization of where to place resources is needed to help pediatric drug developers comply with regulations and set up frameworks for efficient pediatric drug R&D. In this presentation, we will discuss the hierarchy of clinical trial data and how to ascertain the efficiency of each step and arrive at estimates for the numbers of assessments, exposures, participants, etc. Pediatric drug development typically necessitates accessing dozens of sites in multiple countries just for a single study, which entails managing inevitable logistical issues, both planned and unplanned, while having to complete trials in a short time frame with long term follow-up. Responding to these challenges can be accomplished through a stakeholders' working group of drug developers, patient advocacy organizations, academic partners, and regulatory agencies that can establish priorities and deliverables, while enhancing close cooperation and responsive communication. Also critical is the recognition that because of complications ranging from age-based variability in dosage forms to formulation stability, oral dosage forms can be challenging but globally placed pediatric-specific formulation developers are addressing the strong interest in developing alternatives to injectables.

#### Biography

Christopher Milne joined the Center for the Study of Drug Development at the Tufts University School of Medicine (Tufts CSDD) in 1998 as a Senior Research Fellow and has published over 70 book chapters, white papers, and journal articles. Currently, his research interests include: academic-industry collaborations; disease, demographic and market access factors in the emerging markets; incentive programs for pediatric studies, orphan products, neglected diseases, breakthrough therapies, and medical countermeasures (MCMs); and, tracking the progress of new regulatory and research initiatives such as regulatory science, translational medicine, personalized medicine, and FDA User Fee programs.

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