The physiology and maturational processes/timelines in the developing infant/child as key parameters in the toxicokinetic handling of drugs. The biochemical development of the major metabolizing enzymes P450, UDP-glucuronosyltransferases (UGTs), and Sulfotransferases (SULTs) show that some enzymes are higher in fetal life (some P450s and Sulfotransferases) while others develop in the neonatal period generally within the first 2 years (UGTs, some P450s). These biochemical aspects of pediatric sensitivity are coupled with neonatal and pediatric physiological changes including: differences in blood albumin levels, microsomal protein per gram of liver (MPPGL) and changes in liver and kidney volumes and blood flows that occur differentially from 0-2 years of age and then mature during late childhood or adolescence. Because human health risk assessments are most commonly based on rodent data, species-specific pathways that exist in metabolism as well as species differences in common enzymes and transporters with different ontogeny will be compared and contrasted to demonstrate both the utility and limitations of rodent testing for developmental drug exposure.

“Drug Development and Toxicity in Children – where are we going and where have we been?”

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