



SAFETY ASSESSMENT

Neonatal and Juvenile Toxicity Testing

Routes of Administration

- Dermal
- Inhalation (nose-only)
- Intramuscular
- Intravenous (bolus to continuous infusion)
- Oral (gavage)
- Subcutaneous
- Intracerebral

Charles River has the experience, knowledge and capabilities to design and implement efficient, relevant and successful neonatal and juvenile toxicity testing programs for our clients' therapeutic agents. Over the past two decades, we have performed hundreds of studies in neonatal and juvenile animals using a range of species and dose routes to support pediatric drug development.

Recently, there has been a regulatory emphasis on nonclinical safety evaluation in neonates and juveniles by both the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and the Ministry of Health, Labour and Welfare (Japan). These agencies are requesting neonatal and juvenile toxicity testing for a large range of pharmaceutical and biological products. Emphasis is placed on the assessment of specific organ systems, including cardiovascular, gastrointestinal, immune, metabolic, neurological, pulmonary, renal, reproductive and skeletal. Where a therapy is primarily for pediatric use, consideration should be given to combined juvenile and chronic toxicology studies.

Experience

Charles River has successfully assisted in the design and planning of appropriate neonatal and juvenile toxicology testing programs to support clients' registration for pediatric use. The data from such studies is used to characterize risk for both efficacy and safety studies in the pediatric population and, as a result, may support the reduction of the number of children required for pediatric studies. This experience, along with our extensive background data, enables us to undertake full product development programs for a diverse range of new chemical entities and biologics for pediatric use.

Our scientists are well versed in many specialty study designs such as drug abuse liability, endocrine disruption and developmental neurotoxicology. We can also incorporate specialist endpoints into study designs to address specific concerns

EVERY STEP OF THE WAY