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Alan M Hoberman

Charles River Laboratories, USA

Designing reproductive/juvenile animal studies to reduce animal use, while maximizing human translation

The non-clinical studies required to support a new drug application for a large or small molecule drug generally require testing in two species (if appropriate). Approximately 65% of the animals used for these studies are used for the reproductive and developmental toxicity studies (DART). With the introduction of juvenile toxicity studies, usually in one species, the number of animals used has increased significantly. In addition most of these non-clinical studies include extra animals added for the purpose documenting exposure to the drug or the kinetic profile (exposure overtime). Over hundred litters (average about 12 fetuses per litter) and dams can be saved by combining the fertility and early embryonic study (FEED) with the embryo fetal development study (EFD). Low toxicity drugs can be tested in one rather than three studies saving over two hundred dams and litters. Provided sexually mature non-human primates (NHPs) are used in the 90 day study, male and female fertility end points can be added to these studies. In addition the EFD study in NHPs can be combined with the peri-postnatal study (PPND) to eliminate 50% of the NHPs that would be used in a standard program for a biologic or large molecule drug. Micro-sampling (30 µl or less) techniques verses normal sampling techniques (500 µL), can eliminate satellite animals. This can reduce animal usage by another 20% for DART studies and 40% for juvenile toxicity studies. Micro-sampling will also improve the scientific quality of the studies. Specific case studies will be presented.

Biography

Alan M Hoberman is the Global Director of DART and Juvenile Toxicology for Charles River. He has over 40 years of experience in toxicology and is both a Diplomate of American Board of Toxicology and a Fellow of the Academy of Toxicological Sciences. He is the incoming President of the Teratology Society, the first society dedicated to the study of birth defects. He has published more than 85 peer reviewed papers and co-edited the first book on non-clinical pediatric testing.

alan.hoberman@crl.com

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