



Figure 4. Power curves for the detection of rare adverse reproductive malformations from a developmental and reproductive toxicity study. The study is assumed to have 20 litters/group and a 0% background incidence. The vertical dotted line indicates a 10% incidence of an adverse outcome, which would be detected 4.7% with 1 pup/litter 66.4% with 3 pups per litter and 86.5% with 4 pups/litter. Source: Adapted from Blystone et al. (2010).