

Carcinogenicity studies

Studies that use animal models to evaluate the carcinogenic potential of pharmaceuticals. They are also used to test chemicals and food additives. The objectives of carcinogenicity studies are to identify a tumorigenic potential in animals and to assess the relevant risk in humans. Any cause for concern derived from laboratory investigations, animal toxicology studies, and data in humans may lead to a need for carcinogenicity studies. The fundamental considerations in assessing the need for carcinogenicity studies are the maximum duration of patient treatment and any perceived cause for concern arising from other investigations.