

An international appraisal of the minimum duration of chronic animal toxicity studies.

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Publication year: 1992

Journal: Human & experimental toxicology

Authors: Centre for Medicines Research, Carshalton, Surrey, UK.

Society: Centre for Medicines Research

Origin country: UK

DOI: 10.1177/096032719201100302

PMID: 1352109

Source: <https://pubmed.ncbi.nlm.nih.gov/1352109/>

1. There are international differences in regulatory guidelines for the appropriate duration of chronic, two species repeat-dose animal tests for new medicines intended for long-term use in man, ranging from 6 months in Europe to 12 months in Japan and the USA. 2. An adequate data base is necessary to support any challenge to the scientific rationale behind regulatory guidelines with regard to the design, duration and relevance of toxicity tests of new medicines. 3. The Centre for Medicines Research has established an international toxicology data base which has been expanded to enable a comparison of data obtained within 6 months, with information from longer periods, for 154 studies. 4. Although new findings were revealed after 6 months for 9/75 cases for which pathology data are available at 6 and 12 months or longer, and 21/80 with data at 1 or 3 (but not 6 months) and 12 months or longer, in no instance did these influence the decision to drop or further develop the compounds in question. 5. These data suggest that a 6-month period of dosing is all that is routinely required for evaluating the chronic toxic (excluding carcinogenic) potential of a new chemical entity intended for therapeutic use.