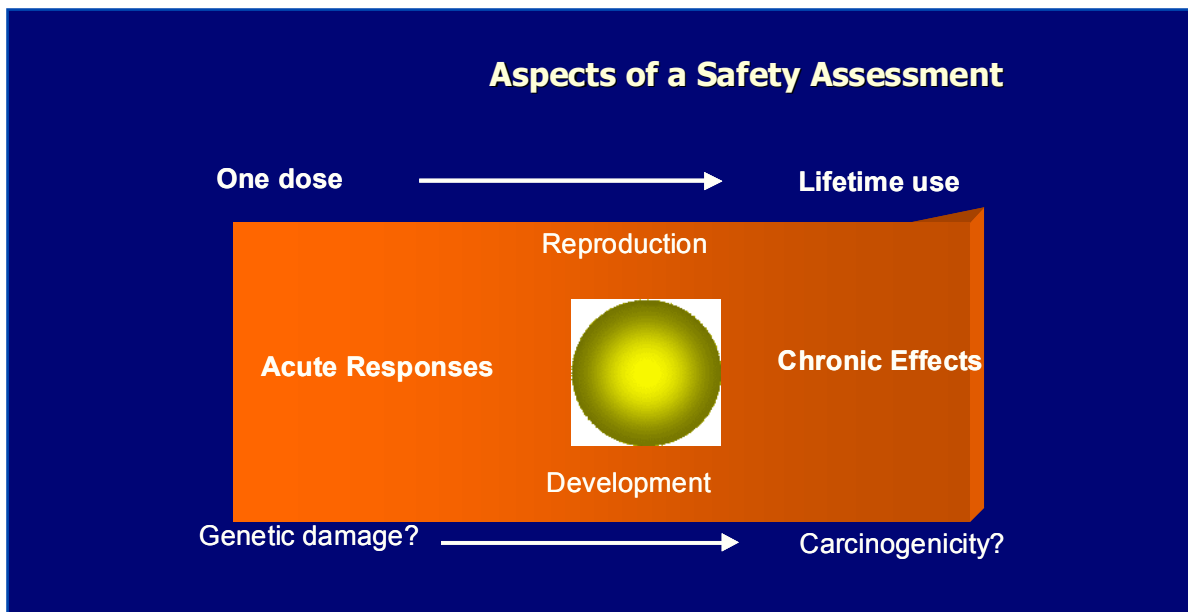


The extent and timing of animal toxicity testing depends on:

- (i) the eventual clinical usage of the medicine (Slide A) with minimal testing needed for medications intended for acute and intermittent usage and a more comprehensive package for chronic usage &:
- (ii) the phase of clinical development (Slide B) with genotoxicity and short term (eg 28 day) tests required prior to short duration Phase I & II clinical studies, longer term (eg 3m/6m/12m) tests needed prior to Phase III and 2 year carcinogenicity testing prior to product approval. Details of the regulations governing toxicity testing are found under the Safety (S) subsections of the ICH guidelines www.ich.org

A.



B.

