

Technical terms

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Bayesian: Statistical methodological approach that assigns probabilities or distributions to parameters based on prior data and applies Bayes' theorem to revise the probabilities and distributions after obtaining the experimental data.

Bernoulli distribution: A discrete distribution having two possible outcomes: $n=0$ and $n=1$, where $n=1$ ("occurs") occurs with probability p and $n=0$ ("does not occur") occurs with probability $q=1-p$, where $0 < p < 1$. In chemical toxicology, such a distribution might describe the probability of a discrete adverse outcome such as animal death or present of tumours i.e. it occurs or does not occur.

Bootstrap: A statistical technique based on multiple resampling. In a bootstrap approach, a probability distribution estimated from observed values is used to generate new samples. For example, based on a random sample of 20 data points in an experiment, the data might be resampled 1,000 times, calculating a standard deviation and a mean each time. The resulting distribution of some quantity of interest (e.g., the standard deviation or the mean) is used to calculate confidence limits or perform statistical tests in computationally complex situations, or where a particular distribution of an estimate or test statistic cannot be assumed.

Categorical Data: Data recorded in categories, either without a natural ordering (sex: male or female), or naturally ordered (**ordinal**, e.g., mild, moderate, or severe).

Confidence Interval: A statistically derived interval (typically consisting of lower and upper bounds) that has a specified probability of containing the true value of some estimated parameter, if the same population is sampled repeatedly. The interval is expected to include the true value of the estimated parameter with a specified confidence, e.g., 95%.

Convergence: In the case of a parameter estimate, approach to a single value with increasing number of computational iterations.

Covariate: An independent variable other than dose that may influence the effect of interest, e.g., age, body weight, sex.

Continuous Data: Data measured on a continuum, e.g., organ weight or blood biomarker concentration.

Coverage (in reference to **Confidence Interval**): The actual (as opposed to theoretical) probability that a population parameter is bounded by the limits of a given confidence interval procedure.

Dichotomise: The process of dividing or classifying objects, data, or events into two groups. For example, 50 animals could be classified into two groups, according to whether their weight exceeds some specified value.

Dichotomous Data (also known as **Quantal Data**): Type of data where an effect may be classified into one of two possible outcomes, e.g., dead or alive, with or without incidence of a specific symptom (e.g., tumour).

Dose-Response Model: A mathematical function that relates or predicts the occurrence or severity of an adverse effect to a given range of doses.

Extra Risk: A measure of the increase in risk of an adverse effect adjusted for the background incidence for the same effect. Extra risk is calculated as follows: $[P(d)-P(0)] / [1-P(0)]$, where P = the probability of an effect and d = dose.

Frank Effect: An obvious or overtly clinically apparent toxic effect.

Goodness-of-Fit Statistic: A statistic that measures the deviation of observed data from predicted or hypothesized values. Some goodness-of-fit statistics can be used in statistical hypothesis tests, leading to rejection (or failure to reject) a model due to lack of an adequate fit.

Log Transformation: The process of taking logarithms of the data. Log transformations are often applied to continuous response data to make the transformed responses satisfy a normality assumption, if the data are lognormally distributed.

Margin of Exposure (MOE): Ratio of a dose that produces a specified effect, to an expected human dose.

Markov chain Monte Carlo (sampling): Markov Chain Monte Carlo sampling provides a class of algorithms for systematic random sampling from high-dimensional probability distributions. Unlike Monte Carlo sampling methods that are able to draw independent samples from a distribution, Markov Chain Monte Carlo methods draw samples where the next sample is dependent on the existing sample, called a Markov Chain.

Ordinal Data: see **Categorical Data**

Point of Departure (PoD): The point where the dose response curve moves away from background. It can be used as a basis for the setting of health-based exposure limits.

Probability Distribution: A statistical description (in the form of a distribution) of the relative probabilities of all possible outcomes of an event.

Quantal Data: see **Dichotomous Data**

Reference Dose (RfD): An estimate of a daily exposure to the human population (including sensitive subpopulations) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

Reference point (RP): see **Point of Departure**.

Supralinear dose response: A dose-response relationship that is proportionately steepest at the lowest levels of exposure.

Uncertainty Factor (UF): A numerical value (often a factor of 3 or 10) used to adjust a NOAEL, LOAEL, or benchmark dose to derive a **reference dose**. Reasons for UFs to be applied as needed are to account for e.g., extrapolation of results in experimental animals to humans, interindividual variability (including sensitive subgroups), extrapolation from a LOAEL to a NOAEL, extrapolation of results from subchronic exposures to chronic exposures, and/or database inadequacies.

Variance: The variance in an experimental measurement remaining after accounting for variance due to the independent variables, e.g., dose, exposure duration, and age.