

Prediction intervals for overdispersed Poisson data and their application to historical controls

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Several OECD guidelines for the regulation of toxicological studies require the validation of the concurrent (negative) control group by historical control limits (HCL). These limits are calculated based on historical control data obtained from prior runs of the same type of study, and should cover the observation(s) from the concurrent control group with a probability of 95%. This talk demonstrates the application of HCL to count data as observed for example in the Ames test (OECD guideline 471) or in reproductive toxicology. The proposed prediction intervals account for the clustered nature of HCD and hence, for overdispersion. Contrary to other applications, different numbers of experimental units (e.g. petri dishes) per control group can be taken into account as an offset variable.