

Decision criteria for the comet assay validation study

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The comet (single cell gel electrophoresis) assay is a genotoxicity test. One of the reported advantages of this assay is that its sensitivity for detecting low levels of DNA damage is greater than that of other genotoxicity tests. Image analysis methods have facilitated the automated measurement of various comet parameters obtained in this assay. On the other hand, the method for interpreting such data completely has not yet been established.

Because the assay is relatively new, an international validation study of the in vivo comet assay is being planned for the primary purpose of evaluating interlaboratory variability and relevance. In order to make the validation study more confirmatory, it is necessary to determine several decision criteria before the study, such as the acceptable degree of interlaboratory variation or a rule for concluding whether the results of the genotoxicity assay are negative or positive. Therefore, a pre-validation study for the further validation study is currently being carried out using 3 chemicals across 5 laboratories.

To date, we have already developed a datasheet for the pre-validation study in order to collect data from the different laboratories and to manage its quality. Besides, as biostatisticians, we have discussed the plan of data analysis with members of the validation management team (VMT). Data of the pre-validation study was collected and fixed by the end of January 2008, and we will have a meeting in March 2008 to discuss the results with the members of the VMT.

In this presentation, we will report what we have discussed about the criteria for the further study based on the results of the pre-validation study.