

EquivTest™ - A CRO Perspective

EquivTest™ reviewed by Independent Data Management - A Leading Irish CRO

Independent Data Management Ltd., is a Contract Research Organisation based in Cork, Ireland. We specialize in clinical trial consultancy and management and pharmacokinetic and biostatistical analysis. Because we analyze data from a large number of bioequivalence studies for sponsors submitting applications to various national regulatory authorities, EquivTest has proved a very useful package.

The first striking feature of EquivTest is its data management capability. The data we receive from crossover trials can be recorded as either multiple variables per subject or multiple records per subject. Rather than having to dictate to our clients which style we require, EquivTest can accommodate both styles. This, together with the broad range of packages supported in the import facility, makes data importation quick and effortless.

Though most pharmacokinetic parameters in a bioequivalence study are analysed using parametric techniques, some need to be analysed using non-parametric techniques. Previously this entailed exporting the relevant data from one statistical package via a text file to a specialized non-parametric package. EquivTest gives us the option of including a non-parametric analysis in the output report. This feature is very useful and especially so when the assumptions underlying parametric analyses are in doubt.

For most bioequivalence studies, the equivalence bounds are 80% to 125% of the reference mean on the logarithmic scale. When the therapeutic window for a drug under investigation is narrow, these bounds need to be narrower. Likewise when the therapeutic window is broader, the bounds can be broader. EquivTest allows the user to specify the equivalence bounds relevant to the particular study protocol.

Another excellent feature is the output report. This report can be tailored to include all or any of the descriptive statistics, Analysis of variance results, Shuirmann's one-sided t-test(s) and nonparametric statistics. The output is clear and concise. Different sections are clearly defined. The report is written in language easily understood by the non-statistician and it can easily be integrated into a final study report.

Since the release of EquivTest, the analysis of bioequivalence studies can be quick, easy and programming-free. All statistical methods required by the FDA and CPMP guidelines are available in one easy-to-use package.

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