



PharmaSoftware Solutions, Inc.

Offering many useful software for design and analysis in pharmaceutical research and development.

www.pharmasoftware.net

BABE Solution 2008

What's BABE Solution 2008 Basic ?

BABE Solution 2008 developed by the PharmaSoftware Solutions, Inc is intended to be the first software package that devoted to the design and analysis of bioavailability (BA)/bioequivalence (BE) studies. This basic version provides statistical analysis for both in vivo bioequivalence and in vitro bioequivalence studies. It is our goal to provide pharmaceutical scientists and biostatisticians a state-of-the-art and user-friendly software for assessment of both in vivo and in vitro bioequivalence in pharmaceutical research and development.

This software consists of two modules: In Vivo ABE (average BE) and In Vitro BE. This basic version provides statistical analysis for a standard two-sequence, two-period (2x2) crossover design for assessment of in vivo ABE. Under the standard 2x2 crossover design, bioequivalence assessment and tests for the period effect, the direct drug effect, and the carryover effects are provided. However, it does not provide statistical inference on the interactions among these effects and the interactions between fixed and random effects.

Developed based on best-seller

BABE Solution 2008 Basic was developed based on the third edition of the book entitled Design and Analysis of Bioavailability and Bioequivalence Studies by Shein-Chung Chow and Jen-pei Liu, which is one of the best sellers at Amazon.com. As indicated in the preface of the third edition of this book, it provides a complete and an overall comprehensive presentation of the latest development in the area of bioavailability and bioequivalence. Regulatory requirements and guidances, scientific/practical issues, and statistical methodology are discussed in details.

Easy to use

BABE Solution 2008 Basic is designed on the basis of user-friendly. It allows the user to either manually input data or to import data from an EXCEL file. The result can be exported to an EXCEL file by different formats. BABE Solution 2008 Basic provides spreadsheet-style tables to specify analysis parameters and expected differences. Quick help walks you through all the steps in the data analysis of both in vivo ABE and in vitro BE studies.

Validation

All functions and procedures of the BABE Solution 2008 Basic have been validated against programs developed based on current existing software such as SAS in the marketplace. In addition, the results obtained from the BABE Solution 2008 Basic were checked against the examples given in the book. BABE Solution 2008 Basic has been tested for computational accuracy across table-specific ranges of parameters. The validation reports for each table contain a list of parameter values tested and the sources were well documented.

Summary Report

BABE Solution 2008 Basic not only provides individual subject plots, mean plots, and plots for preliminarily examination of subject-by-treatment interaction, but also generates a complete summary report for bioavailability/bioequivalence studies based on different data types. The summary report is ready for inclusion in the final study report. BABE Solution 2008 Basic also allows generating useful tables for sensitivity analysis and evaluating specific ranges of study parameters for some given tables.

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