BIOSTAT

STATYSTYKA & PROJEKTOWANIE BADAŃ

STATISTICS & SURVEY MANAGEMENT

BIOSTAT is a modern Statistics and Data Management company which was established in response to the increasing demand for data mining services. We offer outsourcing and data analysis consulting in the areas of biostatistics and clinical trials, pharmacoeconomics, medicine-promoting surveys, HTA and medical research as well as CRM and marketing. Our aim is to help the research community with investigations having non trivial statistical content. We enter into relations with companies, institutions and scientists who use statistical methods in their activity and we conduct and participate in all the stages of the research project. We provide services to the leading pharmaceutical companies and researchers.

Medical research and development of drugs is a complex process with many parameters. Proper data management and sample size optimization may significantly reduce the costs of the research. Business intelligence and data mining are highly useful in various medical projects.

BIOSTAT offers consulting and outsourcing of biostatistics services in the following areas:

SAP Template (Statistical Analysis Plan):

- -Sample size and power calculations.
- -Randomization methods.
- -Studies of endpoints and covariates choice.
- -CRF development.

Data management.

- -Data coding and data entry.
- -e-CRF.
- -Data validation.

Statistical analyses.
Statistical analyses according to the SAP.

- -Interim, subgroup, ad hoc and post hoc analyses.
- -Detection of Bias and Outliers.
- -Quality of Life analyses.
- -Health economic analyses.

Major applications of statistics in medicine:

- Survival analysis

  Survival Analysis is a branch of statistics dealing with death in biological organisms. Death or failure is called an event in this technique. The Kaplan-Meier Estimation for Survival Curves attempts to provide the researchers with a viable interpretation of the data. (standard methods: Cox proportional hazards models, Kaplan Maier method).

- Bioequivalence study

  Bioequivalence (BE) means the absence of a greater-than-allowable difference between the systemic bioavailability of a test product and that of a reference product. The aim of the BE is to check whether the two drugs are bioequivalent (similar). Clinical drug-drug interaction is a key issue in clinical practice, for example of HIV/AIDS treatment. Schuirmann's Two One-sided Tests (TOST) procedure is the preferred statistical method for evaluating a drug-drug interaction effect based on drug systemic exposure as assessed by AUC and Cmax. A Phase 1 drug-drug interaction study is generally considered for drugs that are likely to be administered concomitantly.

- BioStatistics & clinical test studies

  Analyses in the test study are based on the Protocol and Statistical Analysis Plan (SAP). The statistician has the primary responsibility for all stages of a drug's development. At the end, there come the vital tasks of arriving at correct interpretations of the data analyses, formal documentation, presenting the results to managers or regulatory authorities. An outline of the various stages presented, showing how the data analysis is the integral part of the research process is given below.

  ·Pre-clinical. The stage before the new drug may be given to humans. The main objective: to make sure the drug is as safe as can possibly be known, thus allowing it to be given to humans.

  ·Clinical. Investigating a drug on humans. The experiment can be categorised into 4 phases:
  Phase I: experiments are undertaken on healthy volunteers. The aim: to assess the safety of the drug for humans.
  Phase II: The aim: to find the best (optimal) dose.
  Phase III: Experiments investigate the drug on a large number of humans who suffer from the disease. The aim: to understand how variable the results of the investigations are likely to be.
  Phase IV: Commercially oriented. The aim of these experiments may be to show not only that the drug is safe but also that it proves superior effectiveness.

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- Correlation analysis & data dependency

  Correlation analysis and data dependency are methods used to detect the relations between various parameters. Basic methods like correlation coefficient or t-test are applied in every research.

- Data classification

  Data classification can be applied to clinical data. On the basis of taxonomy rules researcher may classify the entity into the particular group.

- Data Clustering

  Clustering has two main applications in the fields of computational biology and bioinformatics. Clustering might be used to build groups of genes with related expression patterns. Such groups often contain functionally related proteins, such as enzymes for a specific pathway. Experiments using expressed sequence tags or DNA microarrays can be a powerful tool for genome annotation. Another application of clustering might be grouping a number of parameters into one homo-genous factor. In sequence analysis, clustering is used to group homologous sequences into gene families. Cluster analysis is also widely used in market research. Market researchers use cluster analysis to define the relationships between different groups of consumers. It may also be used in a new product development.

- HTA & Pharmacoeconomics

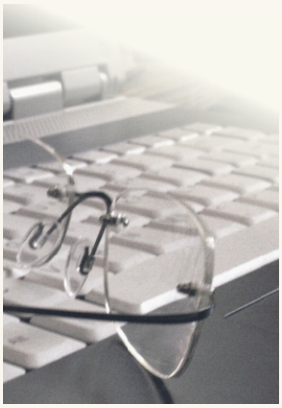
  The idea of Pharmacoeconomical analysis is to compare the value of one pharmaceutical drug or drug therapy to another one, the analysis is based on the costs and benefits (in monetary terms). Pharmacoeconomic measurements include costeffectiveness, cost-benefit, cost-minimization, cost-utility and QALY.

- Various Medical and Biomedical analyses
- CRM & Marketing Analysis

BIOSTAT provides also analytical services to make marketing and sales initiatives more effective. We perform different types of analyses based on our clients' needs, from the structured database analysis of consumer behavior to advanced response models for direct marketing purposes.

Reliable information based on KDD (Knowledge Discovery in Databases) is the major factor of success and business development. CRM (Customer Relationship Management) covers concepts used by companies to manage their relationships with customers and competitors.

BIOSTAT offers consulting and outsourcing of analytical CRM services which include: capture, storage and analysis of customer information. We advice our clients on every aspect of analytical CRM.



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