

Why BioSTAT?

A strategic outsourcing relationship with BioSTAT is a cost-effective means to enhance a company's competitive advantage.

EXPERIENCE

- Since 1994, contract statistical services exclusively for the nonclinical toxicology and animal health industry
- GLP trained statisticians average more than 30 years of industry experience

EXPERTISE

- In-depth knowledge of the unique statistical issues presented by studies such as safety pharmacology, long-term carcinogenicity, reproductive and behavioral.
- More than 2000 nonclinical statistical reports submitted to regulatory agencies
- More than 40 Target Animal Safety statistics reports submitted to CVM
- More than 200 publications including 2011 statistics chapter in <u>Developmental and</u> <u>Reproductive Toxicology, Third Edition (Ch.21)</u> and 2012 statistics chapter in <u>A</u> <u>Comprehensive Guide to Toxicology in Preclinical Drug Development (Ch.31)</u>
- Member of the ILSI expert working group and co-author of its report on <u>Statistical</u> <u>Issues and Techniques Appropriate for Developmental Neurotoxicity Testing (2008)</u>

EXCELLENCE

- Customized services tailored to the specific needs of the individual client
- Dedicated in-house QA services
- GLP and OECD compliant
- <u>QC process</u> in which all statistical aspects of a project are blindly duplicated by a second, independent statistician

VALUE ADDED

- When dictated by a unique study design, sponsor requirements or regulatory guidelines, BioSTAT provides progressive statistical analysis methodology above and beyond the capabilities of in-house resources such as <u>third-party analysis software</u>
- Including an experienced statistician from protocol development through the reporting phase and regulatory review is a cost-effective means to assure the integrity of a study.

