



# BIOESTADÍSTICA, S.C.

An introduction



# WHAT IS BIOESTADÍSTICA, S.C.?

BioEstadística, S.C. (BIO):

- ❖ It is a Latin American consulting company, dedicated to Statistical Methods for Health Sciences Research.
- ❖ Founded in Monterrey, Mexico, it has been serving Latin American health organizations since 1997.
- ❖ It has more than 40 members with postgraduate degrees in areas such as Mathematics, Statistics, Bioinformatics, Genetics, Health Quality, Research Methodology, Medical and SocioMedical Sciences.
- ❖ It applies not only existing statistical techniques, but develops new theory and methodology published in more than 26 top level journals in more than 8 countries.

# OUR MEMBERS PUBLISH THEIR STATISTICAL METHODOLOGY IN:

1. **Annals of Epidemiology (USA) (\*)**
2. Annals of Operations Research (USA)
3. **Bioquimia (México)**
4. **BMC Cancer (UK)**
5. Boletín de la Sociedad Matemática Mexicana (México)
6. Control and Cybernetics (Poland)
7. **Genetics (USA)**
8. **Genetics and Molecular Biology (Brazil)**
9. **Infection and Immunity (USA)**
10. Journal of Agricultural, Biological and Environmental Statistics (USA)
11. Journal of Applied Mathematics and Optimization (USA)
12. Journal of Applied Probability (England)
13. **Journal of Clinical Epidemiology (Netherlands)**
14. Journal of Mathematical Systems Estimation and Control (USA)
15. Journal of Multivariate Analysis (USA)
16. Journal of Optimization Theory and Applications (USA)
17. Journal of Quality Management (England)
18. Journal of Statistical Planning and Inference (Netherlands)
19. **Journal of The National Cancer Institute (USA)**
20. Kybernetika (Czech Republic)
21. SIAM Journal on Control and Optimization (USA)
22. Statistics and Probability Letters (Netherlands)
23. Systems and Control Letters (Netherlands)
24. The Mathematical Association of America (MAA) (USA)
25. **Virology Journal (UK)**
26. Zeitschrift fur Operations Research (Germany)

(\*) Health journals in orange

# MISSION

To collaborate with Health Latin American Institutions to improve overall health indices of the countries in the region.

# VISION TOWARDS 2020

To consolidate itself as a Latin American high performance organization, while maintaining quality service equal to, or higher, than any other similar in the world, to reach the top 10 worldwide.

# CLIENT DISTRIBUTION

We serve researchers from:

- ❖ Mexico since 1997
- ❖ USA since 2004
- ❖ Panama since 2005
- ❖ Argentina since 2007
- ❖ Colombia since 2008
- ❖ Peru since 2008



Until now, we have had more than 400 projects with over 300 customers.

# ORGANIZATION



# DISTRIBUTION OF NODES IN MEXICO



# PRODUCTS

## Consulting and Courses:

- ❖ Methodology: Work with researchers to define, develop or review a protocol or project
- ❖ Database development and electronic hospital records
- ❖ Integration of statistical modules in the system of health institutions that already have Electronic Files
- ❖ Determining the appropriate types of statistical analysis to use
- ❖ Carrying out the required analysis
- ❖ Technical report development
- ❖ Clinical study report preparation and formatting by journal and/or conference standards
- ❖ Health Quality

# INTERACTION AREAS WITH CROs & PHARMAS

“Company” below refers to both **CROs** and **Pharmaceuticals**. **BIO** has offered outsourcing to them in some situations mentioned in the following table.

SITUATION	CROs		PHARMACEUTICALS	
	SMALL	LARGE	SMALL	LARGE
The <b>Company</b> requires sophisticated statistical analyses but lacks specialists with strong training in that field	✓		✓	
The <b>Company</b> needs simple statistical analyses, but wants a <b>validation by an external source</b>	✓	✓	✓	✓
The <b>CRO</b> wants to send (as a value-added feature) <b>not just data to its customers, but all statistical analysis and its conclusions</b> . Although its customer could also make the analysis, sometimes it also seeks for a validation	✓	✓		
The <b>Company's</b> statistical dept. <b>charges a high cost for their work</b> . That is frequent in <b>US or European headquarters</b> . In those cases it is usual to bill among departments or divisions		✓		✓
The <b>CRO</b> wants statisticians to be with them at a meeting with customers but <b>its personnel cannot travel, or it can, but at a high cost</b>		✓		
When its statistical dept. is saturated and additional studies arise that cannot wait	✓	✓	✓	✓
<b>CRO's customers require statistical analysis and/or databases</b> and the <b>CRO</b> do not want to assign human resources to those functions. In such cases, the <b>CRO</b> asks us to give preferential prices to its customers. Furthermore, in our proposal, <b>we specify that discount was granted by recommendation of the CRO</b> (otherwise, that client will have access only to our normal costs)	✓	✓		
Some <b>Pharmaceuticals</b> have a strong statistical dept. but want an <b>independent comparison</b> between some of its products and others from a rival company			✓	✓

# SOME OF THE ACTIVITIES WITH THE PHARMACEUTICAL INDUSTRY

*(only listed those with no confidentiality issues)*

- ❖ Laboratorios PISA
  - ✓ A comparative study on post-cesarean analgesia with "Graten" (morphine sulfate)
- ❖ Glaxo Wellcome Mexico
  - ✓ Comparison of indicators of blood gases and ventilation parameters with and without surfactant
- ❖ Bristol-Myers Squibb - Mead-Johnson Division
  - ✓ Neonatal morbidity and mortality in 104 hospitals in 19 states of Mexico
  - ✓ Technology resources for newborn care, at the same 104 hospitals

# SOME INTERVENTIONS IN DESIGNING PROTOCOLS (PAGE 1 OF 2)

*(only listed those with no confidentiality issues)*

- ❖ Susceptibility to cancer, identification of high risk families
- ❖ Proteolytic and metastatic characterization of the interaction: “neoplastic cells – macrophages” in breast carcinoma
- ❖ Correlation between distance kick-chin and the likelihood of difficult intubation in pediatric surgical patients 1 to 10 Kg
- ❖ Polymorphism of Toll-like receptor genes and their potential association with gastroduodenal diseases related to infection by *Helicobacter pylori*
- ❖ Early and highly sensitive detection of cytomegalovirus in human plasma HIV-positive samples.
- ❖ Gene expression profiles as molecular evidence implicating Human Papilloma Virus involvement in retinoblastoma pathogenesis

# SOME INTERVENTIONS IN DESIGNING PROTOCOLS (PAGE 2 OF 2)

*(only listed those with no confidentiality issues)*

- ❖ Differences in Genome Content among *Helicobacter pylori* Isolates from Patients with Gastritis, Duodenal Ulcer, or Gastric Cancer Reveal Novel Disease-Associated Genes
- ❖ Determination of DNA Damage in Floriculturists Exposed to Mixtures of Pesticides
- ❖ A molecular analysis by gene expression profiling reveals Bik/NBK over expression in sporadic breast tumor samples of Mexican females
- ❖ Molecular analysis of hepatitis B virus "a" determinant in asymptomatic and symptomatic Mexican carriers

# PRODUCTS BY DIVISION

(EXTRACT)

# QUANTITATIVE RESEARCH (BIOSTATISTICS)

- ❖ Epidemiological Studies
- ❖ Design of quantitative studies (surveys, sampling, experimental)
- ❖ Diagnostic tests
- ❖ Analysis of longitudinal data
- ❖ Meta-Analysis
- ❖ Analysis of clinical trials
- ❖ Risk Analysis
- ❖ Statistics for Evidence Based Medicine
- ❖ Survival Analysis
- ❖ Generalized Linear Models
- ❖ Multivariate techniques (factor analysis, principal components, MANOVA)
- ❖ Statistical Software Training:
  - ✓ SAS - Statistical Analysis Systems
  - ✓ SPSS - Statistical Package for the Social Sciences
  - ✓ EPI-INFO - Statistical Software from CDC (Centers for Disease Control and Prevention) and WHO
  - ✓ WinNonlin - Modeling and analysis of PK / PD (Pharmacokinetic / Pharmacodynamic) models
  - ✓ SAGE - Statistical Analysis for Genetic Epidemiology

# BIOINFORMATICS

- ❖ Massive databases
- ❖ XpEI ®: Hospital electronic file
- ❖ Perl Programming
- ❖ Sequence Analysis
- ❖ Design and analysis of microarrays
- ❖ Evolutionary models
- ❖ R and BioConductor

# QUALITATIVE RESEARCH

- ❖ Qualitative techniques to obtain information
- ❖ The in-depth interview
- ❖ The group interview
- ❖ Focus Groups
- ❖ Participatory Research Design
- ❖ Semiotic analysis (content)
- ❖ Bioethics in research in health sciences
- ❖ Systematization of operational experience of health services and/or educational interventions
- ❖ The scientific paper, a qualitative approach
- ❖ Free association technique
- ❖ Pile sort
- ❖ Semi-structured interviews
- ❖ General Qualitative Analysis Software
  - ✓ Antropac
  - ✓ ATLAS/ti - Computer-Aided Text & Multimedia Data Interpretation
  - ✓ Q.S.R. NUD.IST
  - ✓ The Ethnograph: Qualitative Research and Data Analysis Software

# HEALTH QUALITY

## ❖ Consulting

## ❖ Training:

### ✓ Six Sigma in Health for:

- "Executives"
- "Specialists" (green belt)
- "Experts" (green belt)
- "Experts" (black belt)

### ✓ Hospital Management Indicators

- Quality assurance, hospital management indicators
- Organization for quality

# SOME POSSIBILITIES FOR INTERACTION WITH BIO

BIO can collaborate with your organization by outsourcing projects in Latin America, in:

- 1) Protocol development and/or review
- 2) Database design and management
- 3) Statistical analysis
- 4) Writing research results for publication in medical journals and conferences

# CONTACT

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