BIOSTATISTICS & PROGRAMMING

A WEALTH OF EXPERIENCE

… Insightful Study Design and Analysis

With decades of industry experience, our biostatistics and programming team offers insightful analysis and accurate display of clinical data. We have extensive experience in working with FDA statisticians and other reviewers on drug development planning, clinical study design, and statistical analysis issues.

PROMETRIKA's expertise in biostatistics extends beyond that of traditional CRO services to the specialized areas of adaptive design and clinical trial simulations, meta-analyses, PK / PD analyses, analysis of stability data for drug expiration dating, and exploratory analyses in support of publications and industry congresses.

Our commitment to quality and adherence to regulatory requirements necessitates rigorous validation of all statistical output.

PROMETRIKA's Biostatistics Team — A Snapshot

- PhD and Master's level statisticians average 19 years of industry experience in all phases of clinical development
- SAS® programmers average 14 years of industry experience

OUR SERVICES

- Study Design & Protocol Development
- Sample Size Estimation & Randomization
- Statistical Analysis Plan Preparation
- SAS® Programming
- Interim Analyses
- Statistical Writing for CSRs
- Statistical Consulting
- ISS, ISE and Statistical Sections of NDAs / EU Submissions
- Natural History & Registry Design & Analysis
- Meta Analyses
- IVRS Validation
- IDMC Support
- SDTM Conversion Programming & Validation
- Adaptive Clinical Trial Design & Analyses
- PK/PD Analyses
- Product Commercialization & Phase 4 Support

FOR CLIENT–FOCUSED CLINICAL DEVELOPMENT SOLUTIONS…

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