



Research, Optimized.

Using Biostatistics Providers

With biostatistical services increasingly outsourced, the proper design, oversight and review of those services are mission-critical to today's biopharmas

W&A SERVICES

Pragmatic Solutions

We design solutions and help you actually implement your strategies

Domain Expert

Senior industry managers who understand what you do

For 20 Years, Known to Know®

Leading the industry's focus on process improvement since 1993

Many biopharmas, whether they are new to Clinical Development, or simply finding their staff is overwhelmed with work, are relying on third-party providers of basic and advanced biostatistical services. However the staff in charge of this outsourcing may not have experience in doing so, or be unfamiliar with the tasks being provided. Nonetheless the responsibility for timeliness, accuracy and insight remain. The result may be that you are receiving services, but are uncertain as to their quality, cost-effectiveness or appropriateness, or you may be certain there are performance issues that are unresolved.

In this regard, Waife & Associates, Inc. offers the following consulting assistance to help improve your use of third-party biostatistics providers:

Project Management and reviewing of biostatistics deliverables from third parties (CROs). Such deliverables include Clinical Trial Protocols; Statistical Analysis Plans (SAP); Tables, figures and listings; Statistical reports and analysis interpretation; Manuscripts.

Selecting a biostatistics CRO that fits your skills, timeline, budget, and culture.

Evaluating and remediating the biostatistics services you employ.

Defining, developing, implementing and maintaining of harmonized quality processes in biostatistics and statistical programming.

Assisting with the conceptualization, planning, design and analysis of clinical research studies.

Providing strategic and hands-on support in identifying the appropriate statistical pathway for development for customer-oriented solutions.

Ensuring appropriate performance metrics are defined and measured.

For more information on these Services, or to discuss these topics in more detail, please contact Detlef Nehrdich, nehrdich@waife.com. For more information on Waife & Associates, Inc., please visit us at www.waife.com.

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