Analytic Expertise and Quality Deliverables

Our biostatistics group has broad experience with analytical techniques in outcomes research. We can help you develop value messages that resonate with each of your stakeholders.

We understand the special challenges associated with analysis of endpoints in oncology clinical trials and other sources, and routinely provide the link between our clients' clinical statistics and outcomes research groups. We are GCP-compliant and provide high-quality, auditable tables for submissions.

We help you develop and commercialize your products with our wide range of analytic expertise and deliverables.

Data Sources:
• Clinical trial studies (Phase I–IV)
• Registries and other prospective observational studies
• Scientific literature
• Claims data
• Electronic medical records

Analytic Expertise:
• Health-related quality of life (HRQoL)
• Q-TWiST (quality-adjusted time without symptoms or toxicities)
• Exploratory and post hoc queries
• Resource utilization
• Non-randomized comparisons
• Systematic literature reviews
• Meta-analysis, including indirect and mixed treatment comparisons

Deliverables:
• Protocols
• Statistical analysis plans (SAPs)
• Tables, listings, and figures
• Clinical study reports
• Supplementary evidence and support for HTA submissions
• Response to regulatory questions
• Peer-reviewed publications

Our deliverables often directly lead to additional analyses for publications. The result is faster development of supplementary evidence to support value messages for regulatory submissions and payer discussions.

We have conducted studies across the clinical development lifecycle for numerous cancer types, including breast, colorectal, bladder, renal cell, NSCLC, ovarian, prostate, lung, gastric, and head and neck cancers.
See How We’ve Helped Others

An Observational Cohort Study of Patients with HER2-Positive Metastatic Breast Cancer
We were chosen as the statistical coordinating center for a large multi-year patient registry. Selected based on our biostatistical expertise and experience with the special challenges associated with observational studies, we planned the routine analysis reports and implemented hypothesis-driven analyses. Our statisticians participated on the external advisory board and collaborated with the company in presenting data at internal and external scientific meetings.

Analyses of Quality-of-Life for New Chemotherapy
Our statisticians performed a series of analyses on QOL data from clinical trials for a new chemotherapeutic agent. Treatment outcomes and toxicities were evaluated simultaneously using the survival-based Q-TWiST approach. We provided supplemental support to regulatory applications, and the work led to multiple posters at cancer conferences such as ASCO, SABCS, and EBCC. Results were published in Current Medical Research & Opinion and Breast Cancer Research and Treatment.

Meta-Analysis on the Relationship Between Progression and Survival in Metastatic Breast Cancer
We performed a meta-analysis to assess the association between time to disease progression and overall survival in metastatic breast cancer studies based on a systematic literature review. Results were published in British Journal of Cancer.

Meta-Analysis to Estimate the Association Between Asthma and Cancer Incidence
We searched the National Library of Medicine Gateway to identify observational studies of cancer incidence in asthma and included any case-control or cohort study of incident cancers or of cancer mortality that met the predefined inclusion criteria. The study found no significant association between asthma and cancer incidence. Results were published in Annals of Allergy, Asthma & Immunology.

Rely On Our Thought Leaders
We are adept with data from multiple sources and experienced in complex analytical techniques including mixed models, pattern-mixture, propensity scoring, and sample weighting. We select and implement state-of-the-art analytical methodologies based on project requirements and the type of data.

The broad study experience and expert use of survival techniques makes us particularly well-suited for exploring post hoc requests from oncology clinical trial data, including analyses of subgroups, QOL, and health care utilization data.

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