



Clinical Programming & Statistical Services

United BioSource Corporation (UBC) is a specialized clinical data and regulatory service provider focused on the design, execution and interpretation of complex clinical development programs from early stage development through regulatory submission.

Experienced Data Ambassadors

UBC's senior statisticians have an average of over 20 years of industry experience with junior statisticians maintaining an average of over six years of industry experience. All have a minimum of a master's degree. UBC couples this analytical expertise with a strong programmatic staff. Our programming department has 240 combined years of real-world SAS® experience and maintains thought leadership in SAS programming, including educating and publishing on the subject. Over half of our programming department holds master's degrees and we provide ongoing training and education to maintain the highest quality standards. This scientifically enriched team means we are more than mere number crunchers; we are data ambassadors.

Statistics & Clinical Programming Staff Experience

With our extremely low turnover rate, our experienced programmers maintain project continuity from inception to completion.

We specialize in knowledge transfer and comprehend the science behind the numbers. Whether your audience is a regulatory agency, an in-licensing group or a co-development partner, we supply the strongest possible presentation of your data. UBC knows evidence matters.

The statistics and clinical programming teams have expertise in the following areas of statistical analysis and reporting:

- Study Design & Protocol Development
- Endpoint Selection & Validation
- Statistical Methodology Consistent with ICH Guidelines
- Clinical Development Plans
- Sample Size Considerations
- Analysis Plans
- Tabulations, Listings & Graphical Presentations
- Data Integration, Data Warehousing, Meta-Analysis & Data Mining
- Statistical Reports (Interim, CTR, CTD)
- DMC & SMC Support & Participation
- Statistical Regulatory Representation
- Adaptive Design

Success Through Understanding

UBC believes strong communication and collaboration lead to success. From the onset, a dedicated project manager provides individualized attention throughout the entire project.

UBC accelerates the generation, analysis and communication of real-world evidence.

A key component to effective communication is a solid understanding of the data being analyzed. Our statistical and programming leads organize project kick-off meetings to make certain the programming team understands the key project components prior to beginning their respective programs. This includes review of the CRF design, the statistical analysis plan, key points of the protocol and any other issues that may impact programming.

Our statisticians and programmers are actively involved in the clinical trial process as a whole. This provides them with a better understanding of the data and any other issues that may arise as a study is conducted. Their involvement in the early stages assists in effective data collection and cleaning. This is especially important when working with efficacy data.

Quality Process & Attention to Detail

UBC leads the way in quality statistical programming and quality metrics confirm that output created by our programming department is 98% error free. We attribute this success to an extremely thorough validation process. We validate output each time data are updated to ensure that the quality of the output has not been adversely affected by new data.

There are a minimum of two programmers assigned to each project to ensure the quality of our product. One programmer is assigned to production programming and the second programmer to validation. Both programs are written independently to guarantee the accuracy of datasets and tables. Our statisticians validate all efficacy results and review output for consistency. Listings are validated against datasets and figures are validated against tables.

Customization & Client Satisfaction

Our flexibility and ability to customize programs and output are the key to the success of each project and the satisfaction of our clients. We pride ourselves in catering to the specific needs of each of our clients.

We possess abundant experience in all therapeutic areas, especially oncology, and understand the unique development environment involved in executing complex clinical study designs.

Our statisticians and programmers are experts in handling sensitive information regarding blinding and un-blinding of treatment groups for interim analysis and data monitoring committees (DMCs). The statistics and programming teams have a thorough understanding of CDISC requirements and regularly produces data and documentation in compliance with CDISC standards.

We greatly value client relationships and take pride in never outsourcing. All work and documentation are prepared on site for every study, and we provide all SAS programs along with standard project documentation upon project completion.

Due to the high quality of our work, integrity and valuable relationships we have built with our clients, over 90% of our business is from repeat customers annually.

For more information about UBC's specialty clinical solutions, call us in the U.S. at +1 215 591 2880 or in the E.U. at +44 (0) 208 834 0100. Or email us at info@unitedbiosource.com.