FIRMA
CLINICAL RESEARCH
*Expert Insights | Quality Outcomes*

# DATA SERVICES:

Speed regulatory submissions with efficient, high-quality data and analyses

CASE STUDIES

The Firma team consists of PhD- and MS-level professionals adhering to a single set of global standard operating procedures, offering their detailed and extensive knowledge of pharmaceutical development to benefit your entire data management and biostatistics planning, execution, and analysis. Our approach to data management and biostatistics begins with a broad knowledge base in all aspects of the clinical trial process and a dedication to cross-training all team members prior to initiation of the study. With robust, scalable, and software-independent processes, we efficiently capture, maintain, clean, and deliver data for your project regardless of phase, therapeutic area, size, or method of data capture.

**Learn how three clients relied on Firma Data Services to deliver speedy database integration and summary analyses to meet regulatory requirements.**

## EXPEDITED WORKFLOWS AND RESCUE LEADS TO AGENCY APPROVAL

**Client:** Mid-sized pharmaceutical company

**Project Focus:** Full data management and biostatistics- service rescue

**Request:** After the client's original CRO filed for bankruptcy, the client requested Firma to rescue two Phase 1 studies within a 2.5-month timeline. Services included:

- Database build
- Data entry from the hard copy of CRFs
- Query management
- Medical coding
- Database lock
- Statistical analysis
- CSR writing

**Approach:** To meet the timeline, Firma organized and deployed three teams to complete the tasks in parallel. While team members built the databases, the lead statistician wrote the SAPs and mock tables, and the medical writer created the CSR shells.

**Results:** The client's ANDA was successfully submitted in accordance with the original timeline at the end of a 2.5 month contract with Firma, and was approved by the FDA.

## FLEXIBLE AND TIMELY INTEGRATION OF ADDITIONAL ANALYSES

**Client:** Small biotech company

**Project Focus:** NDA submission support

**Request:** The client originally engaged Firma to support an NDA submission which included:

- ISS from 27 studies
- ISE from two pivotal studies
- Medical writing for the NDA submission

Another CRO was contracted to perform, statistical analysis for the two pivotal studies; however, after missing the timeline for the first pivotal study, the client subsequently expanded Firma's responsibilities to include the statistical analysis for the second pivotal study.

**Approach:** Firma assigned the module of SDTM data sets from the 27 Phase 1 and 2 studies to the same SAS programmer to preserve time and cost. Three teams were created to address analyses for ISS, ISE, and second pivotal study.

Additionally, three medical writers were brought on to write the ISS, ISE, and CSR for the pivotal study. All team members worked in parallel using the SAP and protocol for creating the ISS, ISE summaries, and CSR shells.

**Results:** Firma converted the original 27 studies from non-CDISC-compliant data sets to CDISC-compliant data sets within seven months. Additionally, the expanded scope of work incorporating the second pivotal trial had complete statistical analysis so the client could submit their NDA within 45 days after database lock, meeting their corporate timelines.

## MEETING CORPORATE FDA TIMELINES WITH CONFIDENT AND COMPREHENSIVE LEADERSHIP

**Client:** Large pharmaceutical company

**Project Focus:** FDA-requested analyses

**Request:** The client submitted an NDA that had been supported by another CRO. The FDA requested several different analyses due within 45 days. Firma was brought in to take over the additional analyses after the initial CRO could not support the timeline.

**Approach:** Together, a clinician, two statisticians, and two SAS programmers reviewed the original analyses results and new analyses proposed by the FDA. Firma then assigned a statistician and a clinician to review the protocols, CSR, and NDA submissions. In parallel, a SAS programmer studied the CRFs and the database structure, while the two statisticians and two SAS programmers performed the analyses.

**Results:** The additional analyses were performed and submitted to the client in 30 days. As the result of this successful support, the NDA was approved by FDA and Firma received an "Outstanding Achievement Award" from the client.

## FIRMA DATA SERVICES

For more information on how you can speed regulatory submissions with efficient, high-quality data and analyses, email **sales@firmaclinical.com** or visit **firmaclinical.com.**