Case Study:

DELIVERING LARGE-SCALE PHASE III OBESITY PROGRAM WITH SPEED, QUALITY AND PATIENT-CENTRIC EXECUTION

BACKGROUND

Obesity is one of the fastest-growing therapeutic areas in clinical research, driven by increasing global prevalence and the emergence of novel GLP-1 therapies. As these programs expand into large Phase III studies, Sponsors face mounting operational challenges, including rapid enrollment, high-volume data collection, long treatment durations and maintaining participant engagement throughout the study.

Medpace has supported a pivotal Phase III program evaluating GLP-1 therapy in adults with obesity – in participants with and without type 2 diabetes. These studies required rapid startup, large-scale enrollment and proactive patient retention strategies to ensure data quality while protecting critical study endpoints.

STUDY OVERVIEW

~5,700 Participants Enrolled Across Program

~150 Total Sites

~80 Week Treatment Duration (with dose escalation followed by long-term maintenance therapy)

Full-service CRO support, including Clinical Trial Management, Regulatory Affairs, Data Management, Medical Monitoring, ePRO, IRT, ECG Core Laboratory, Central Laboratory, and Bioanalytical Laboratory services.

RESULTS

Accelerated Study Startup: Activated all study sites within 12 weeks, enabling rapid initiation across the program.

Exceptional Enrollment Performance: Completed enrollment of all participants in the non-diabetic pivotal study within approximately four months – finishing two months ahead of projected timelines. Enrollment for obesity plus diabetes study was completed in approximately eight months.

Strong Patient Retention: Through the first 30 weeks of treatment, approximately 85% of participants remained on the study, reflecting the effectiveness of proactive engagement and retention strategies during this long-duration trial.

High-Quality Operational Execution: Successfully managed thousands of participant visits each week while maintaining data quality through centralized oversight, proactive monitoring, and structured data review processes.

STUDY CHALLENGES

Managing High-Volume Data at Scale: Rapid enrollment and weekly participant visits generated a significant volume of clinical data, requiring continuous oversight to maintain data quality and prevent operational bottlenecks.

Maintaining Patient Retention Throughout a Long-Duration Trial: Obesity studies utilizing placebo arms present unique retention challenges, as participants who are not experiencing weight loss may suspect they are receiving placebo and become more likely to discontinue participation.

Managing GLP-1 Dose Titration and Tolerability: Consistent management of GLP-1 side effects and tolerability across investigators is essential to support patient safety, adherence and endpoint integrity. A systematic process was developed to identify participants at risk allowing for proactive engagement by the investigator. Study tools and step-by-step guides were developed to support this outreach to participants. Investigator training on the dose escalation process and options to support participants through dose titration was also a key strategy for enhancing retention.

MEDPACE SOLUTIONS

Proactive Data Oversight: Developed real-time operational dashboards to monitor data entry, query rates, source data verification and monitoring forecasts, enabling study teams to rapidly identify emerging issues. Batch data cleaning milestones and focused CRA assignments at high-enrolling sites minimized backlog while maintaining data quality throughout enrollment.

Patient-Centric Retention Strategies: Implemented comprehensive patient and site education beginning at screening to establish realistic expectations around placebo assignment and the importance of remaining in the study. Additional retention initiatives – including lifestyle support resources, nutritional meal services, individualized counseling and predictive dashboards that identified participants at elevated risk for dropout – enabled study teams to intervene before disengagement occurred.

Integrated Clinical Support for GLP-1 Management: Designed a purpose-built IRT system capable of dose interruption and down-titration to support investigators managing tolerability concerns. Standardized treatment algorithms, comprehensive investigator training and regular access to Medpace clinical experts through scheduled case consultation sessions promoted consistent patient management across all sites while supporting retention and endpoint protection.

AN INDUSTRY LEADER IN OBESITY CLINICAL RESEARCH

Medpace brings deep therapeutic expertise and a fully integrated operational model to obesity clinical development. Our in-house medical experts, Advanced Clinical Practitioners, clinical operations teams and centralized support services work collaboratively to address the unique recruitment, retention and operational challenges associated with large-scale obesity studies. By combining patient-centric trial execution with rigorous endpoint protection, Medpace helps Sponsors accelerate development while maintaining the quality and scientific integrity required for successful Phase III programs.

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