› CASE STUDY

VERISTAT

Rescuing a Global Program for NDA Success

Achieving FDA Approval: How Veristat's Strategic Consulting and Biometrics Leadership Enabled Regulatory Success

Background

A sponsor developing a combination therapy was deep into Phase 3 development when the FDA provided comments on the program's statistical analysis plans (SAPs). The sponsor needed a statistician with regulatory experience and technical precision to adequately interpret the FDA feedback and respond accordingly. Facing fast-approaching deadlines and a globally distributed team, the sponsor engaged Veristat for expert guidance. With the Veristat team's ability to rapidly respond, what began as strategic consulting on modifications to the SAP quickly evolved into a full biostatistics and programming effort, including a globally dispersed Veristat programming team to execute the Phase 3 end of study outputs and provide end-to-end NDA support.

Sponsor Challenge

With FDA review underway and timelines tightening, the sponsor determined they needed additional expertise to meet regulatory expectations for statistical clarity, technical depth, and documentation standards. The FDA's feedback on the two Phase 3 study SAPs which had been previously written by a third-party CRO without extensive regulatory experience required the expansion of technical components, including drafting estimand statements, defining intercurrent events, and strategic planning for the consistent collection, interpretation, and documentation of intercurrent events as the studies neared completion.

The sponsor needed not only a technical solution but a strategic partner capable of leading complex discussions, crafting key regulatory messaging, and delivering high-quality data packages under pressure.

STUDY DEMOGRAPHICS

STUDY PHASE
- Rescuing two Phase 3 global trials and New Drug Application (NDA)

INDICATION
- A chronic condition in adults

SERVICES PROVIDED
- Strategic Consulting
- Biostatistics and Programming
- SAP Authoring and Response to FDA Feedback
- SDTM, ADaM, and TLF Programming
- Cross-Regional Execution
- NDA Submission and FDA Information Request Support

Key challenges included

- Re-authoring of existing SAPs, including:
  - Estimand definition and alignment with ICH E9(R1)
  - Identification and operationalization of intercurrent events from multiple data sources
  - Missing data strategies and advanced standard error estimation for complex modeling
- Rapid startup of SAP-related activities and accelerated timelines with coordination across global teams in the US and across APAC and Europe.
- Preparation of high-quality regulatory documentation and strategic responses for FDA
- Initiation of Phase 3 programming activities shortly prior to scheduled database lock
- Execution of biostatistics and programming delivery across two studies involving cross-regional programming teams and oversight

Veristat Solution

Veristat assumed authorship of the SAPs, elevating them to meet FDA standards with a clear structure and a technically accurate presentation. This included defining estimands, developing methods to handle intercurrent events and missing data, and integrating advanced statistical strategies to support regulatory confidence.

Veristat also led the full biostatistics and programming execution for two global Phase 3 trials, followed by the NDA. The Phase 3 trial programming activities were initiated shortly prior to database lock, expediting the timelines and requiring an efficient resourcing strategy. Veristat accessed its global team with concurrent activities for the two studies simultaneously led by Taiwan-based and European-based programming teams, coordination by a single lead statistician, and oversight from a strategic consultant to ensure consistency across the program. The global Veristat team recorded decisions and met regularly to ensure consistency between the Phase 3 study data handling conventions and analysis methods.

Veristat also provided strategic guidance throughout the NDA process. The biostatistics, programming, and strategic consulting team prepared detailed FDA response packages and contributed to labeling language throughout the FDA review period.

Impact

- FDA approval of a novel therapy for a chronic condition in adults
- Rescue and turnaround of a high-risk global program
- Cross-regional biostatistics and programming execution delivered on an accelerated timeline
- Regulatory information requests and labeling support
- Ongoing collaboration with the sponsor, demonstrating a “one-team” approach