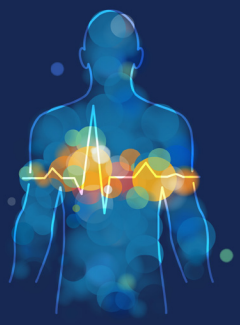
Case Study:

ACCELERATING SUCCESS IN DEVICE TRIALS: DELIVERING RAPID ACTIVATION AND ENROLLMENT FOR A 198-PATIENT U.S. STUDY



BACKGROUND

A medical device Sponsor engaged Medpace to support a pivotal U.S.-based study evaluating a 12-lead ECG synthesis software. The device aimed to demonstrate diagnostic accuracy compared to a standard FDA-cleared 12-lead ECG.

The following case study outlines strategies that Medpace took to accelerate site activation and enroll to database lock within an extremely tight timeline.

STUDY CHALLENGES

Although the patient population was accessible and the study procedures were straightforward, the Sponsor imposed aggressive timelines. This meant the full trial – spanning site activation, patient enrollment, and database lock – had to be completed in under six months. Ensuring consistent execution across multiple large academic centers added complexity, as these institutions typically have longer internal start-up timelines.

RESULTS

Despite the compressed timeline, all study objectives were met through disciplined planning and execution:

- Site activation to study closure in ~3.5 months
- All 198 patients enrolled across five U.S. sites without delays or recruitment issues
- Database lock achieved in under six weeks post-LPLV
- No screen failures due to minimal eligibility criteria and outpatient study design
- High compliance and low dropout due to same-day procedures

THE SOLUTIONS

Medpace's clinical operations, regulatory, and data management teams closely partnered with the Sponsor to drive rapid execution and ensure all study milestones were met or exceeded.

Key strategies included:

PROACTIVE START-UP PLANNING

- A kick-off meeting was scheduled within two weeks of award to initiate activities immediately.
- Regulatory teams used historical site performance data to identify potential bottlenecks and prioritized document collection accordingly.
- Sites were asked to commit to target submission dates for regulatory documents, enabling focused follow-up and accountability.

COLLABORATIVE SPONSOR AND SITE ENGAGEMENT

- Medpace leveraged strong Sponsor-site relationships to encourage responsiveness, particularly during activation.
- Early and routine escalation processes ensured delays were addressed quickly, with the Sponsor assisting when necessary.

OPERATIONAL OVERSIGHT

- Enrollment monitoring was continuous, allowing rapid ramp-up at high-performing sites. Most sites enrolled multiple patients per day.
- The same-day study procedure design minimized dropout risk and eliminated the need for follow-up visits.
- CRAs sent sites pre-closeout task lists to ensure data entry and query resolution were completed ahead of closeout visits.

DATA MANAGEMENT

- Medpace's ClinTrak® EDC system supported real-time data collection and monitoring.
- The Medpace data management team remained in close communication with sites and CRAs, allowing for a clean database and rapid lock within six weeks of LPLV.