

Post-Database-Lock Request Delivered in 2 Days!

CHALLENGE

The sponsor was a large medical device provider bringing to market an ablation catheter for the treatment of persistent atrial fibrillation. BioTel Research was contracted to provide ECG, Holter, and TTM data processing. The favorable results from the sponsor's study allowed them to apply for a premarket approval supplement from the FDA.

During subsequent conversations with the FDA, it came to light that 3 additional ECGs were required. **This request had to be completed within 3 business days, after database lock.**

FDA REQUIRED

- **Additional ECG reads**
- **3-business-day turnaround, after database lock**

SOLUTION

BioTel Research worked closely with the sponsor and our internal teams to outline the fastest path possible. Same study medical readers were on call to interpret new ECGs when made available. Data managers expedited the processing of new data. Project managers coordinated cross-departmental workflows. Regulatory guaranteed that BTR's actions adhered to the highest standards of compliance.

Most importantly, **BioTel Research put our sponsor's needs first and proceeded with the work at hand, without indulging in contractual considerations.**

RESULT

A standard turnaround time for this kind of request is typically 2-3 weeks. **BioTel Research was able to deliver results to our sponsor in just 2 days!** The sponsor's meeting with the FDA was successful, and approval of their device was announced 2 weeks later.