

Unique Cardiac Safety Service Solution for Multiple Sclerosis Study



CHALLENGE

The sponsor was a large biopharmaceutical company engaged in an aftermarket study for early-stage multiple sclerosis patients. To ensure participant safety and to expedite discharge from study clinics, **the FDA required same-day predose/postdose cardiac safety testing**. Specific testing requirements for each participant included:

- Candidate receives predose ECG. Test **results must be available within 30 mins**.
- Patient is approved for study contingent on favorable ECG results.
- Approved participant is administered drug.
- Participant receives a postdose ECG. Test results must be available within 30 mins.
- Participant is released contingent on favorable ECG results.

Timely ECG interpretation and report turnaround was essential for achieving the required same-day cardiac testing. Thirty-minute ECG result turnaround times were significantly shorter than the standard 2–3 days required for most clinical trials.

FDA REQUIRED

- ***Predose/Postdose Cardiac Safety Testing***
- ***Aftermarket Study***
- ***Early-Stage Multiple Sclerosis***
- ***30-Min. ECG Result Turnaround Times***

SOLUTION

As the chosen outsourcing partner, BioTel Research (BTR) worked closely with the sponsor to develop a unique service solution involving medical, project management, and technology-based perspectives to meet the specific request from the regulatory authorities.

BTR designed and implemented an automated workflow customized for the sponsor, that enabled:

- Timely transmission of ECG data from study sites to BTR's medical team.
- Automated distribution of data and receipt notification to remote Harvard cardiologists for interpretation.
- Reliable publishing and sharing of report results via an online portal, accessible by study sites.

RESULT

BTR was able to consistently average ECG report **turnaround times well below the 30-minute regulatory requirement — often returning results in less than 15 minutes**. The sponsor was able to tap into the resources of a trusted research partner with whom they had worked previously to develop a unique solution. Since 2012, this study continues to generate approximately 10–20 ECGs per day, Monday–Friday, from 8am–9pm. BTR has never missed a beat!