

# Quality Control & Professional Analysis Protect Study Integrity



## CHALLENGE

The sponsor was a mid-size biotech company engaged in a Phase II cardiac safety study. BioTel Research was contracted to provide central ECG data collection and analysis for study participants. Early in the analysis process, **one of our board-certified cardiologists observed that ECG data for several study participants from the same site looked similar.**

He informed our Chief Medical Officer, who performed an independent review of the ECGs along with three other doctors. Each of them provided their findings. There was an agreement that the ECGs from four different subjects look identical.

## FDA REQUIRED

- *Phase II Cardiac Safety Study*
- *Central ECG data collection and analysis*

## SOLUTION

BioTel Research promptly informed the sponsor regarding concern with the site's data integrity. The sponsor reviewed the evidence and subsequently:

1. hired independent cardiologists to confirm our findings, and
2. initiated a site audit on the location from which the ECG data originated.

The sponsor's independent cardiologists confirmed the findings of our medical team.

Furthermore, **the site audit that was conducted revealed workflow processes that compromised the integrity of the ECG data** being shared with BioTel Research for analysis.

## RESULT

The sponsor terminated the site with compromised data, and excluded the data from the clinical trial findings.

Thanks to the vigilance, attention to detail, and thorough quality analysis on the part of our BioTel Research cardiologists, the **sponsor was able to preserve the data integrity of the study and continue with the clinical trial.**