FIVE REASONS TO RETHINK PAPER ECGs

Why gamble with site-managed ECG collection?
Cardiac safety issues are among the most common reasons for promising drugs being halted in development and not brought to market

Inaccurate cardiac safety data can put your patients — and trial — at unnecessary risk. Therefore, accurately identifying potential problems is crucial to keeping your trial on track.

However, if you rely on site-managed ECGs, you may be risking data quality, which could extend study timelines, increase costs and, most importantly, place patients, trials and compounds at risk.

In this eBook we’ll discuss approaches for centralized ECG data collection to enable you to:

> Protect your compound
> Protect trial participants
> Improve patient enrollment and study efficiencies
PROTECT YOUR COMPOUND

1. Nearly 80% of the time, cardiologists and other physicians cannot recognize a long QT when they see one

Sites may claim to be proficient at reading ECGs, but how skilled are they? A 2005 study of more than 900 physicians tells a different story: While QT experts correctly recognized a long QT 96% of the time, cardiologists and other physicians only got it right 22% and 21% of the time, respectively. Morphology issues are also challenging to identify. By taking this gamble with data quality, sponsors who rely on site-managed ECG analysis are putting their compounds at risk of termination due to inaccurate QT readings.

2. Site-managed ECG screening errors can later result in false positive QT signals

If a site under-measures QTc at baseline, but the patient’s QTc is correctly measured later on in the trial, the compound under study will appear to be responsible for an increase in QTc. At a minimum, this may require further investigation and explanation to regulators. Worse, a false positive signal for drug-induced QT prolongation could lead to delays or termination of the trial and possibly the compound.

IMPROVE PATIENT ENROLLMENT AND STUDY EFFICIENCIES

Patient recruitment takes longer with site-managed ECG measurements

In 2015, ERT analyzed 270,000 ECGs from multiple oncology studies where patient eligibility was determined by site-managed ECG measurements. We concluded that as many as 45% of the patients excluded due to prolonged QTc were actually eligible for enrollment when correctly evaluated through centralized ECG measurement. Similar data trends have been documented in therapeutic areas beyond oncology. In an environment where every day of clinical development averages $37,000 or more in operational costs, sponsors can ill afford to exclude suitable patients and the resulting delays in meeting recruitment goals and trial completion.

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PROTECT YOUR PATIENTS

4 Site ECG measurements lead to unnecessary interruptions in treatment
The same ERT analysis of ECGs from multiple oncology studies found that up to 77% of dosing interruptions based on site-managed QTc measurements were unnecessary, as the centralized QTc measurements were considerably lower. By making decisions about dose interruptions based on site-managed ECGs, sponsors may be denying cancer patients potentially life-saving medications and might even eliminate them from the trial.

5 Site-managed ECGs delay recognition of patient safety issues
When sites manage ECGs, they produce a paper ECG without a digital file. The measurements must be manually entered into the CRF or EDC system, risking transcription errors and query delays. Since the ECGs are not saved as digital files, they are not accessible for risk-based monitoring and cannot be submitted to the FDA as required. With paper ECGs, perhaps the greatest risk is that study teams do not receive real-time alerts or notifications when a site finds a safety issue—potentially jeopardizing patient safety across the trial. Furthermore, if site investigators are not experienced cardiologists, they may miss important safety findings entirely.

ECG CENTRALIZATION MITIGATES RISKS, PROTECTS COMPOUNDS AND PATIENTS

In today’s environment where drug development costs and timelines continue to escalate, sponsors cannot afford to gamble with data collection methods that put their compounds and study patients at risk. By centralizing analysis through trained and experienced QT experts, trial sponsors gain confidence in ECG accuracy, overcome the challenge of inter-reader variability caused by site-managed readings and yield the highest quality data to give their compounds the greatest chance for success.
ERT Cardiac Safety solutions have supported more than 500 cardiac safety-related drug approvals across 7,700+ studies and are built upon decades of insight into what global regulatory bodies want to see in protocol design and analysis to prove a compound’s cardiac safety. By centralizing ECG collection and analysis with a reliable ERT solution, sponsors gain confidence in the quality of important cardiac safety data, delivered through near real-time analytics, centralized surveillance and more monitoring options for immediate visibility to the highest quality data. And, because our expertly trained cardiologists monitor, review and report on every ECG test, sponsors can rest assured that trials, compounds and patients are not at risk.

WATCH A WEBINAR AT ERT.COM/FIVEREASONS TO LEARN MORE.

Learn how ERT minimizes risk and delivers the highest quality cardiac safety data for your clinical development programs.
ABOUT ERT

ERT is a global data and technology company that minimizes uncertainty and risk in clinical trials so that customers can move ahead with confidence. With nearly 50 years of clinical and therapeutic experience, ERT balances knowledge of what works with a vision for what’s next, so we can adapt without compromising standards.

Powered by the company’s EXPERT® technology platform, ERT’s solutions enhance trial oversight, enable site optimization, increase patient engagement and measure the efficacy of new clinical treatments while ensuring patient safety. Since 2014, more than half of all FDA drug approvals came from ERT-supported studies. Pharma companies, biotechs and CROs have relied on ERT solutions in 10,000+ studies spanning more than three million patients to date. By identifying trial risks before they become problems, ERT enables customers to bring clinical treatments to patients quickly — and with confidence.