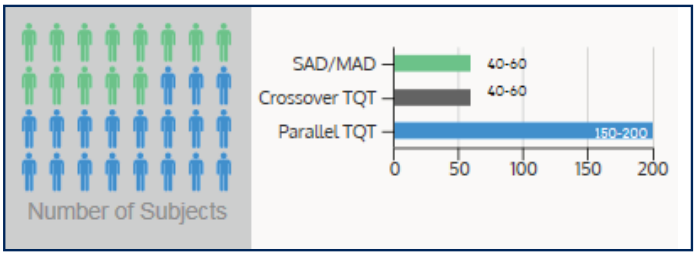
REPLACING THE TQT WITH EXPOSURE-QT RESPONSE STUDY

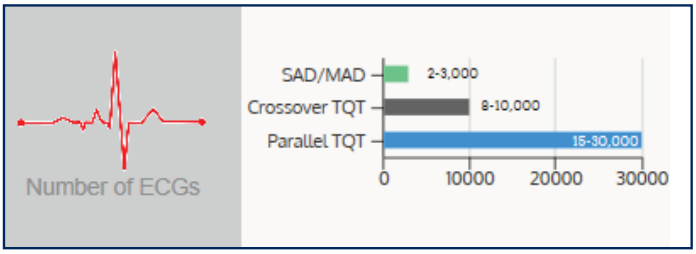
The ICH E14 guidance document entitled The Clinical Evaluation Of QT/QTc Interval Prolongation and Proarrhythmic Potential For Nonantiarrhythmic Drugs, which introduced the concept of the Through QT (TQT), study was recently revised to include the opportunity to demonstrate the cardiac safety of a new drug byutilizing Exposure-QT response study data in dose escalation and other studies.

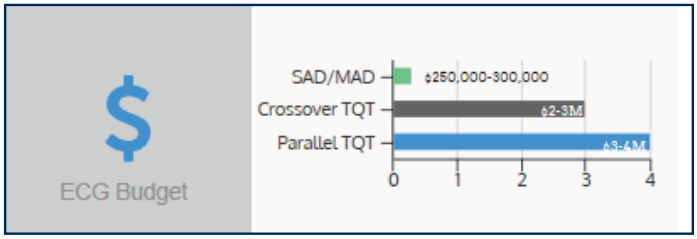
This now gives sponsors a choice between TQT and Exposure-QT studies. Every new drug will require a cardiac safety study prior to regulatory approval. Traditionally, this has been in the form of Through QT study. A recent revision to regulatory guidance allows for cardiac safety to be established with an Exposure-QT Response study.

According to the FDA, "the 'thorough QT/QTc study' is intended to determine whether the drug has a threshold pharmacologic effect on cardiac repolarization, as detected by QT/QTc prolongation." Now, this can be performed by an Exposure-QT study instead.

This is a significant shift that can provide information around delayed repolarization and allow an early decision to halt, or definitive evidence no TQT study will be needed. A demonstrated lack of QT signal removes cardiac risk, and provides a better negotiating position in the event of a sale.







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