



Integrated approach to TQT

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 [iCardiac Technologies](#)

 [Spacelabs Healthcare](#)

 [Charles River Laboratories](#)

 [Cardiac Safety Network](#)

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ROCHESTER, N.Y.-With an eye on making it easier for sponsor companies to conduct Thorough QT (TQT) cardiac safety studies, [iCardiac Technologies](#), [Spacelabs Healthcare](#), and [Charles River Laboratories](#) recently launched the Cardiac Safety Network to provide an integrated TQT offering. The companies' intent is to make it easier and less expensive for drug developers to conduct the studies, which can determine whether a drug has the potential to cause dangerous heart arrhythmias and often require contracting multiple companies to do the work.

"At Spacelabs we think we have a bit of an advantage in that we are focused in our clinical services division on cardiac safety and with the [Cardiac Safety Network](#) we can offer a one-stop-shop for sponsors," says Jim Roop, president of clinical services for Spacelabs. "Because of our size and this focus, we are able to provide work that takes into account the unique demands of our sponsors."

But beyond the FDA-required TQT studies, the Cardiac Safety Network can also provide sponsors with additional data that may help them develop a deeper understanding of their drug's heart safety-and that is where iCardiac comes in.

Founded in early 2006, iCardiac's deep data set, derived from more than 30 years of research in ventricular arrhythmias and repolarization developed at the [University of Rochester](#), allowed it to create an analytical tool that can not only perform TQT, but also includes what the company calls Beyond QT, a comprehensive repolarization analysis using advanced ECG-based biomarkers.

According to Sasha Latypova, executive VP and co-founder of iCardiac, the company is able to take the digital ECG information and measure it digitally, work that until now has been performed manually. "Typically, a cardiologist would (use) calipers and measure from the beginning of the Q to the end of the T," says Latypova. "What we offer is an improvement in the precision of this measurement of between 20 and 30 percent compared to the cardiologist. This allows us to reduce the number of subjects needed to conduct a study and do it faster."

That is not the only benefit of using iCardiac's data, however, Latypova points out. In addition to QT measurement and analysis, the company has also developed algorithms and discovered a number of biomarkers that allow it to more accurately predict potential adverse effects on the heart.

"The Advanced ECG biomarkers are able to show specific information that has been shown to be more predictive of risk of arrhythmia," says Latypova.

From where Roop sits, this information can be extremely important to the sponsors they serve in terms of time and money saved, as well as potentially identifying adverse affects that may not be indicated in a TQT study.

"Eventually this information may be part of the standard operating procedures," he says. "But we are highly regulated and it will take some time for adoption and for [these methods] to become accepted."

To that end, work is already underway as researchers at the University of Rochester, led by Dr. Norman Stockbridge, are working with the FDA under a recent NIH grant to develop new regulatory standards for advanced ECG biomarkers.

Meantime, iCardiac, through the Cardiac Safety Network, has found a workable model that allows it move its services into the clinic without the need to broaden the focus of the 22-person company.

"We are able to provide more information to sponsors at a cost that is not higher than others in the market," Latypova notes. "This allows us to partner with Spacelabs and gain access to their expertise and implementation of studies. This way we can concentrate on continuing to improve our product and provide sponsors with a single point of contact for these studies."

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