

CRO Analytics Sets Sights on Site Quality

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CRO Analytics and the Association of Clinical Research Professionals are partnering to develop a more holistic approach to clinical trial site quality.

The caliber of site operations has traditionally been measured quantitatively, says Peter Malamis, co-founder and CEO of CRO Analytics. Sponsors and sites have judged themselves on numerical metrics based on time and quantity — the ability to get the first patient enrolled in a trial by a certain date or to meet patient enrollment deadlines.

As such, time and quantity are often surrogates for quality, Malamis notes. To measure quality, you really have to measure quality, he says. “It’s a very natural thing to measure, like measuring how fast the car goes, but that doesn’t tell you anything about the quality of the car,” Malamis tells *CTA*.

Using more qualitative benchmarks to determine clinical trial quality at the site level will give sites, sponsors and CROs a better overall picture of trials, and eventually lead to reduced trial time and costs, Malamis stresses.

It can also help to standardize measurements of site quality across multiple therapeutic areas, he says, noting that one trial’s enrollment rate can’t be used to judge enrollment in another trial in a different therapeutic area. Knowing the quality of services provided or the quality of operations carried out can transcend these barriers, he says.

This will help to assess the quality not just of individual trials but also of trials and sites overall, Malamis says. It can also help companies manage sponsor-site or sponsor-CRO relationships.

The joint effort aims to develop a statistically validated data collection system akin to CRO Analytics’ Performer system to get feedback from investigators, study coordinators and other site staff on multiple aspects of site quality, including trial protocol, budget, documentation support and the investigator meeting (*CTA*, [February](#)).

The partners expect to begin collecting data in June and agree on a set of preliminary assessment questions by the end of the summer. — Lena Freund