

# FDANEWS

## Trial Quality System Improves Enrollment, Efficiencies

A new, first-of-its-kind clinical trial quality system created by CRO Analytics could help sites and sponsors track enrollment months earlier than conventional methods, experts say.

Trials frequently miss their benchmark for enrolling a full complement of patients, but don't realize this until months later, says Michael Howley, the company's co-founder and chief science officer. With Performer, sites and sponsors are alerted as soon as an enrollment deadline passes.

The system can also take into account varying enrollment needs for different types of clinical trials, says co-founder and CEO Peter Malamis. For example, a 100-day enrollment deadline may be appropriate for a large cardiovascular trial, but not for a smaller trial evaluating rare disease treatments. Moreover, the system can alert sponsors and sites to problems with marketing materials, recruitment and training of investigators, and the utility of meetings, he adds.

### CRO Involvement

Julia Amo, chief operating officer at ACT Oncology, one of two contract research organizations to jump on board with Performer, says the system addresses issues that study start-ups often overlook. For instance, it has very directed survey questions relating to the initial phases of a trial, which allow sites and CROs to pinpoint where they're going wrong.

Sites and sponsors can also enter information into the system over the course of the trial and receive feedback from CRO Analytics on any red flags that arise, Amo says.

"In our system," says Howley, "if one of those metrics goes red, we can call [the sponsor] and say you are about to have recruiting problems in this trial because you had a really bad investigator meeting. It's likely they're going to underperform, and you need to fix that before there's a problem."

Howley believes more sponsors will turn to Performer to improve efficiencies in clinical research. "There are far too many trials that are still over budget and over time, and the current approaches to measuring performance have not gotten them the insights they need to fix the problems," he says.

To that end, Performer tracks sponsor satisfaction with sites and CROs, notes Amo. "Other tools let us know our clients were satisfied," she tells *CTA*. "This tool specifically let us know in comparison to our competitors where we were strong and where we were weak, so we could address those accordingly." — Lena Freund