

Finding Good Sites in Today's Competitive Site Landscape

The biopharmaceutical industry now spends \$500 million on Big Data in the hopes of finding great investigators and streamlining trials — and yet 23 percent of sites never enroll a single patient and 80 percent of all trials are still delayed.

“Big Data alone doesn't necessarily lead to better decisions,” said Suzanne Caruso, vice president of clinical solutions at WCG. “It's really no better than just kind of guessing. We now have so much information about investigators in the public domain that we don't know how to choose them. We get bogged down and aren't sure what the key predictors are.”

Meanwhile, the industry is wasting an average of \$1.6 million per trial due to slow enrollment, and site activation now takes a month longer than it did last year, she said.

WCG has developed methods for sponsors to drill down on all the data that's available on sites, said Caruso. For instance, WCG knows who's consistently performing at high levels, who's currently enrolling, who works in what therapeutic area, who just finished up a study and has the capacity for another.

With the advent of better technology for storing and quickly analyzing this data, the company now can easily run a search to help sponsors pick the sites that are best for their studies, said Caruso, adding that not all of this information is in the public domain.

WCG boasts contacts for 140,000 investigators, relationships with 2,700 institutions, enrollment performance on 85 percent of all FDA-regulated investigators and data that

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—Suzanne Caruso, vice president of clinical solutions, WCG

are trusted, as WCG works with 95 percent of all industry-sponsored protocols, said Caruso.

Last spring, WCG bought ThreeWire, a patient recruitment, enrollment and retention firm that sends assistants to sites to help investigators with whatever they need on the ground. Additionally, data from ThreeWire helps WCG gather robust intelligence on investigator performance which, in turn, helps the company drill down on what exactly it is that each individual investigator likes, needs and may want going forward.

Using their data to hone in so tightly on the best investigators — and which good investigators could easily be great — WCG helps sponsors avoid other modes used in order to get the most out of sites, an example of which is site groups.

Feasibility questionnaires, traditionally used to determine whether a site is a good fit for a study, aren't useful as they stand, but rather are “sites trying to sell themselves,” Caruso said.

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One of the biggest enemies of a sponsor looking for great sites is competition from other sponsors, said Caruso. Many high performing sites, especially those that focus on a specific therapeutic area, will have multiple sponsors jockeying to have the site take on their study at any one time. Steer clear of busy sites like that, advised Caruso.

“A site that has many studies enrolling will be overwhelmed,” she said. “Patients who might be good for your study will be sitting there unnoticed. Coordinators will be rushed and unfamiliar with your information. I would rather have a site that has few relationships with other sponsors.”

Best, then, to use sites that are experienced — those that don't have many studies currently enrolling, said Caruso, adding that WCG can tell clients which sites have studies enrolling vs. which sites have studies that have stopped enrolling— this represents an opportunity for sponsors.

Peering into the WCG database, Caruso says she can see who enrolls fastest, and shockingly even to her, that small and mid-size pharma companies enroll most quickly.

“That's incredible to me, with the amount of investment large pharma is putting into Big Data on this.”

WIRB-Copernicus data can also tell clients whether an investigator charges a lot, an average amount or comes in low when compared with fair market value, Caruso

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said. Key opinion leaders (KOIs), she said, are expensive and “not worth it.”

“I gear toward medium or low, but with the same randomization rates,” she said.

She added that WIRB-Copernicus

provides report cards for academic medical institutions that do research so they can see how they rate compared to other academic medical institutions.

When asked by audience members what

the phenotype is for a high-quality investigator within an academic medical institution, Caruso responded, “One who has been a sub investigator for a KOI and is trying to make a mark.” 