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Insider Insights:

Gregg Sweet, Integrated Clinical Trial Services

CWWeekly's semi-monthly company profile feature, Insider Insights, interviews executives of companies and organizations in the clinical trials space. Writer Ronald Rosenberg sat down with Gregg Sweet, co-founder and vice president, strategy, of Integrated Clinical Trial Services

Q In your 20+ years of experience, what changes have you seen in the attitudes and outlook of clinical trial participants? Have more complex protocols affected retention and, if so, how have you dealt with it?

A In the last 20 years, I don't think the attitudes of clinical trial participants have changed all that much. Obviously, with more protocols out there, there is more competition in the marketplace for getting people into trials. The negative press that surrounds a lot of issues has a little bit of impact, but that has always been there. I am not sure patients are any less likely to participate in a trial. It all comes down to the relationship they have with their physicians—and their physicians' attitudes toward trials.

In the past, we've seen the physician as the gatekeeper for a patient, referring him to another physician's trial. I think the focus really is on the patient's attitude, which is directly tied to the physician's attitude or a family member's experience. I am not sure if there really has been a change in attitudes.

Every complex protocol impacts retention. But retention always begins at the recruitment level. It is a matter of spelling out what is involved in the trial at the very beginning—during the informed consent or the pre-screening process, depending on how the site operates. But once expectations are established between the patient and the research physician, it is just a matter of good communication.

The big mistake we see in some companies' protocols is they try to address retention too late in the process. They address it once they discover they have a retention issue, rather than at the beginning by building a decent communication model among the patient, the study coordinator and the referring physician.

Q In the last five to 10 years, how has the use of social media affected working with sponsors and CROs and increased efficiencies in centralized patient enrollment and retention?

A We like to say all recruitment is local recruitment. So whether you apply a centralized strategy that includes social media as one of its elements or you do everything direct to site, it's still local recruitment. The sites are located in a particular area and the participants are going to come from within that area, so we really have to address all of our centralized operations as local operations.

Social media helps with that. We have used social media extremely successfully in fostering relationships with sites. But we find some sponsors still are reticent to get involved. They don't understand how they can control the conversations that go on within social media platforms. We do several things that allow us to moderate discussions so if a bad comment comes up we can eliminate it. If a comment comes up that is self-promotional for somebody's book we can take it out.

What social media does is put a social face on the site—a friendly face, a human

Headquarters: Raleigh, N.C.
Year founded: 2003
Description: A clinical trials support company that takes targeted approaches to each study's unique requirements, ICTS has evolved into a full-service organization for clinical trial services, offering specific targeted site optimization, educational platforms and enrollment solutions. It serves all stages of development, from pre-trial preparation, patient recruitment, retention and compliance through to pre-launch transition. In January 2011 the two founders bought out the other three partners to streamline management and begin expansion.
Officers: Tom Sturgis, co-founder and CEO
Gregg Sweet, co-founder and vice president, strategy
Ken Wallace, vice president, clinical operations
Offices: Raleigh, N.C., and Atlanta, Ga.
Employees: 15
Customers: a mix of small and medium-sized pharma companies, CROs and the NIH
Clinical trials: 4 in 2014; 40 in the past five years, including a large NIH study in 2013
Web site: www.icts.us

face, if you will. In centralized recruitment, one of the most difficult things to organize is finding patients from outside the practice. How do we humanize that site? How do we make the site's communication introduction more palatable for patients? They are scared. They have a condition. If it's a chronic condition, it is something they have dealt with for a very long time. They have gone through trial and error, because everybody's body chemistry is different. They react to drugs differently. Social media really allows us to introduce sites in a more human environment than strictly an advertisement.

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Gregg Sweet, co-founder and vice president, strategy, Integrated Clinical Trial Services

A Recently you announced a joint venture with Clinical Trial Marketing Communications to create Integrated Clinical Trial Marketing Services. How it will work?

Q I've known Ken Wallace, founder of Clinical Trial Marketing Communications (CTMC), since 1997. We have always appreciated the work each other's company was doing. We actually have worked with Ken on and off since 2004—he came to us for video production services several years ago, and we went to him for public relations.

We have evolved, along with patient recruitment. Today, what clients really are looking for is: how can my patient recruitment program help me down the road in terms of not only getting patients in the door of my local sites, but also how the methodology being utilized can impact retention compliance within my study.

With this joint venture, we still will look at every protocol as an individual protocol.We still are going to find out the attitudes of people with this particular type of disease. What are they scared of? What things cause a disturbance in their daily life? What types of messaging will be best in reaching this particular person? How much time do we have to deliver that message effectively? Is the time from the date they sign the informed consent to the time they are actually randomized long? Will we have to work with sites to try to maintain patient interest during this time?

The process is not any different. Now we have three minds at the big table when we go in and examine protocols. The joint venture is very similar to a pharma and a biotech joint venture, working under one name yet still operating two companies.

Q What are some of the questionable practices some patient recruitment firms still carry out, and can they be eliminated through customized strategies, targeted site optimization and education platforms?

A The really cool thing about customizing every strategy is that you have this huge tool box, which has multiple partnerships that we developed and worked with over the years. Those are important and essential elements, because what we can do is pick apart protocols, and instead of having two, three or four tools to go to, we have this enormous tool box. It has everything from EMR (electronic medical records) data mining capabilities for sites to potentially referring sites.

We have the ability to send people directly to sites and act as assistant study coordinators, and to truly deliver local messages on behalf of sites. That is incredibly important. So when we are picking apart a protocol, we're using everything available, instead of just what is in the profit center of our business.

The budget always is going to be a huge consideration for anything we do and allows us to roll out what we like to call a 'continuous contingency strategy,' meaning we start with the most cost-efficient means and we end with the least cost-efficient means, if necessary.

We don't have a large corporate structure. Everyone at the top level of this company can make a decision and the rest of us will stand by it. So we can react that much more quickly. There is no cookie cutter or red tape factor, in which you have a very stringent management structure that requires you to go through multiple levels of decision-making.

Q Given the push to tap potential advocacy groups and involve study volunteers with the protocol early, where do you see the future of patient recruitment in the next three to five years?

A There has been a long-term push to work with patient advocacy groups. However, there is a dichotomy in terms of self- interest on the part of the advocacy groups and the sponsors. Sponsors want to involve advocacy groups and utilize their marketing capabilities to reach patients. The advocates want to keep an arm's length distance from the pharma companies. They need the pharma dollars in terms of helping with their fundraising, but they want to make sure there are no strings attached—and for a good reason.

So, we understand pharma wants to get involved with advocacy and advocacy wants to keep pharma at arm's length, and that really is not going to change. Unless you have an NIH comparative study, for which the NIH can partner with an advocacy

program, the reality is you are not going to be able to tap into the marketing resources efficiently.

If you want patient advocacy groups as part of your program, you have to start very early in terms of building relationships with those groups. So while pharma would love us to get more involved, it really is quite difficult. That said, the really cool thing about social media, especially Facebook, is that it is the online advocacy arena for clinical trial participants, chronic patients and even people with acute conditions. We are finding everyone and their brother can set up a Facebook page and talk about their conditions.

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—Gregg Sweet, co-founder and vice president, strategy, Integrated Clinical Trial Services

As a recruitment specialist, we understand how Facebook develops interest groups and associations where you can sign up and identify yourself as a type 2 diabetes patient, for example. But we also understand how certain key words are utilized in discussions throughout Facebook, and how Facebook has the ability to put messages in front of people on their behalf.

This allows us to communicate directly with people in advocacy groups, people talking about caregiving for any condition, and that has brought it into a centralized arena in which we can start these discussions. Having these discussions with advocates on Facebook allows us to take two or three steps out of the roadblock that exists between formal advocacy associations and clinical trials.