cwweekly

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Special Article Reprint

Study Broker

An interview with Sarah Ebner, President

Investigator Support Services, Chicago, Ill.

How and why was Investigator Support Services founded?

I had worked in an academic center for several years as a research administrator and observed many inefficiencies in the way it was managing the business end of research. A couple of areas—primarily budget negotiation, patient recruitment and identification of new studies—seemed to be poorly managed because the people handling those duties were all nurses or doctors. That wasn't their core skill set. The desire to help physicians get involved in studies and independent sites build their businesses by identifying new trials for them was what prompted me to found ISS.

What is ISS' business model?

What we offer sponsors is a large network of independent research sites that are screened according to quality indicators and matched to studies based on sponsor requirements. We've done extensive background checks on each of the sites we're affiliated with. Based on a set of criteria that we use to evaluate and mitigate the risk of affiliating with individual sites, we accept about 40% of the interested sites. When sites indicate their interest in a study, we pre-qualify them for that specific trial by assessing their investigator questionnaires, prior trial experience and sponsor requirements before submitting appropriate sites for sponsor consideration. The refined group of pre-qualified investigators we submit closely matches what the sponsor is looking for, and our selection rate is almost 60%. Study performance is what ultimately determines our reputation for delivering quality sites, which is also the reason sponsors and contract research organizations [CROs] continue coming to ISS for potential sites.

What we offer sites is a steady stream of trial opportunities we've identified that are matched to those sites' capabilities and therapeutic interests. We offer, on average, 25 new studies each month. Most sites don't see 25 because part of ISS' value is that we identify and filter a broad range of studies to provide new opportunities that meet individual sites' needs. We provide access to studies that sites wouldn't have otherwise found—we want to supplement experienced sites' access to trials, not supplant their existing efforts. Our sites, on average, have experience working on 90 clinical trials. Many of them are quite large themselves and are looking to maintain a high level of research activity. For some sites, just getting one or two studies from us is plenty and well worth the affiliation. Other sites are interested in many more.

We have non-exclusive contracts with our sites. If they're selected for the study and if the study moves forward, they pay a fee to us. We give sites a couple of different options, including terms

Year founded: 1992
Employees: 10
Sites: 400 in U.S., Canada and Mexico; 1,000 in India through partnership with SMO
PIs: 1,500 in U.S., Canada and Mexico; 1,300 in India
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based on a percentage of the budget, a flat fee and sliding scale arrangements. One of the things we found necessary and beneficial for everyone involved is to be accommodating to meet the needs of sites, so the agreements do have some flexibility.

Do you do any contract and budget negotiation on behalf of sites?

No, we do not. The sites negotiate their own budgets and contracts with the sponsor or CRO. We have found that both the sites and the sponsors and CROs prefer that approach, for the most part. There are some who have interest in a central contract, but we trust that the sites will negotiate with their best interest in mind and pay us should the study move forward. I know that some organizations like ours are involved in contracting or named as a third-party payee for the study, but such a small piece of the budget goes to us that I didn't feel we needed to be money managers as well.

What differentiates ISS from other study brokers?

Quality assurance and process improvement. We've seen competitors come into study brokering with messages promoting larger site networks and the speed of referrals, wher as ISS focuses on identifying the most qualified sites for each study. This is accomplished by critically evaluating sites from the start, discussing trial requirements with the sponsor or CRO to make the best match and continually tracking site performance and sponsor feedback. We've built a lot of SOPs [standard operating procedures], and we maintain those as well as the processes around the way we evaluate and submit sites. We're also focused on improving our algorithm for site selection and trying to build a model where we can identify factors that predict site performance.

What challenges do you face?

Confusion in the marketplace regarding the various business models. Sponsors and CROs that are unclear on our model might think we're an SMO [site management organization] or a TMO [trial management organization]. The definitions for groups of sites are like moving targets, so explaining and re-explaining our structure and services can be a challenge.

The economic decline is also a challenge. There's been a little bit of a slowdown in the volume of studies. We've also seen sites struggle because their margins are very tight. We get paid only when our sites are paid, so we see some impact from both the slowdown and the historically slow payment of investigators.

How has the clinical research industry changed?

From the industry perspective, pharmaceutical companies and CROs are getting more sophisticated in the way they capture performance feedback. For site performance benchmarks, a lot of what the industry relies on is self-reported capability—'I can enroll 15 patients and I have all this equipment and my staff is experienced in this and that,'—but where's the proof? I've seen larger sponsors and CROs work on really measuring performance. Some of them have built a feedback loop to determine how quickly sites are enrolling their first patient and so on. We are trying to do the same.

What are your plans for growth?

ISS currently has affiliations with sites in India, Mexico and Canada. Expanding into additional countries outside the United States is definitely something we're interested in. We receive occasional requests from companies that are interested in identifying sites in particular regions of the world, so our growth in that area would be based on the requests that we get and the way the industry is shifting. We will also have some growth of our U.S. site network. There are some specialty areas that we're very interested in expanding into—for example, oncology and pediatrics—and we continue to develop affiliations with sites in all other therapeutic areas. We're doing quite a bit of outreach to research sites to make them aware of our services, our position in the marketplace and the benefits we provide to independent research sites.