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Connecting With The Patient And Improving Results In Patient Recruitment And Engagement



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It seems obvious that focusing on the patient is what you would do to improve patient recruitment, right? Is this what the industry has been doing in the past or has the focus just been on the number of patients and related data? E.B. McLindon, Senior Vice President, Site and Patient Solutions, explains how ICON is taking a different approach with its Integrated Site Network and how getting more connected with the patient and easing the burden is really making a difference to enrollment rates.

Why did a CRO decide to acquire a site network?

ICON acquired a clinical research site network because we wanted to get closer to patients and physicians. By acquiring PMG, we would learn more about operational management at the site level and we would also learn a lot more about what appeals – and doesn't appeal – to patients.

We were also looking at using electronic medical records [EMR] as a pull-through for patient recruiting. The Integrated Site Network service model was of particular interest since it becomes the central trial unit for a health care system. Operating at that level, our site network team has access to EMR through business associate agreements and can match patients into studies. There are many companies

out there – some CROs and some service providers – that are accessing EMR and trying to develop big data and heat maps. ICON's approach is to go directly to the patient.

Patient matching is even more necessary now because if you look at the evolving drug development marketplace, a vast percentage of drugs in development are no longer looking for walk-around populations. They are more complex and looking for comorbidities. You really have to know what motivates the patient to participate and stay engaged throughout the study.

Our Integrated Site Network team knows the patients and has relationships with the physicians. The team can combine these at the point of care and offer clinical research as a care option. It's a viable model not just for today, but for the future. As you look at where the health care systems are going and the disruption with groups like Google and Amazon coming into the health care space, there is a need to be able to get direct access to the patient population.

How does the connecting with the patient improve patient recruitment and engagement?

What makes the Integrated Site Network model of more value is the ability to not just know who the patients are, but to get their timely feedback. Our "Patient Voice" program connects directly with the patient to get an understanding of what they are interested in and what is viable. We can ask patient populations specific questions about a particular protocol or a particular technology that we are thinking about deploying to collect data. For example, sometimes patients like electronic data capture options





such as Bring Your Own Device [BYOD] and sometimes they don't, so it's good to get their feedback ahead of time as opposed to forcing another device, which can add a burden and impact on retention. Hearing the patient opinion and being able to adjust the way we operate at the site level allows us to bring greater efficiencies to our sponsors.

At the same time, we have also engaged many of the network physicians in the process of protocol review. Combining the patient and site voice further upstream in the process of development often yields better outcomes. Our focus as we work with sites, not just network sites, but also other alliance sites in our virtual network is to ease the burden for sites as well as patients to participate in clinical trials. If you know ahead of time what the burden might be and make conducting the study easier, you can help the site and the patient to overcome barriers and you will get better data and a better result for the sponsor.

How does an Integrated Site Network translate into efficiencies in conducting clinical trials?

The easiest way to explain it is with a brief case study. We had a sponsor who came to us for a Phase II interventional program. They were only looking for 60 patients in the study, but they wanted to engage 20 sites. They were anticipating that each site was going to enroll only three patients because of the complexity of the study. We worked with the client on an alternative strategy. Our Integrated Site Network's central feasibility team did an analysis and patient matching, which identified patients ahead of time. We realized we could identify more patients per site in at least the same time frame. With this alternative approach, although we only fired up half the number of sites, we enrolled twice the number of patients per site and had almost half the projected number of screen failures. We were also able to get the enrollment done in almost half the amount of time. What was the end result? We saved the client time and money.

There are several ways that ICON is helping sponsors improve the

speed and cost of drug development. Our Integrated Site Network is part of a mosaic that we are deploying for our clients in order to help deliver value to their development plans.

What other kind of efficiencies does an Integrated Site Network bring?

Some of the timing on the front end is saved. Another thing that is equally valuable is the reliability of the feasibility data from sites. According to industry statistics, 35% of sites that initiate studies enroll zero or just a few patients, which is usually a direct correlation to feasibility. With our model, we get more reliable, accurate data about the number of patients projected against what sites actually recruit. This increases predictability and reduces time in the overall process.

Does drug development need to move toward the model of integrating clinical research and health care?

Clinical research has always been a care option in oncology. Our Integrated Site Network model has enabled us to expand this across all therapeutic areas. Because our team is embedded inside a health system, it's easier for them to promote research as a care option since they are in the same office and the same building as the health care providers and their patients.

We can also support physicians who are eager to get into research, but don't necessarily know how. In one case when the health care system began working with our Integrated Site Network, they had only eight physicians engaged in research and after just 18 months they had 24 physicians in research. They not only tripled the number of physicians working in research, but they increased the number of patients involved in research fivefold. The efficiency that this has created at the site level for patients and doctors is what then drives better outcomes for our clients. Being able to connect with the patient and physicians and increase their participation is the value of our model.