IT'S ALL ABOUT RELATIONSHIPS

Jeff Zucker explains the key to improving study site performance

The relationships between sponsors, CROs and study sites can present challenges to a clinical research program, with the way these parties interact having a significant impact on study success. With the growing trend towards patient-centric trials, sites and investigators are increasingly left out of the process, and need to be re-engaged. It is crucial for sponsors and CROs to balance patient-focused activities with increased site engagement, to forge and maintain strong relationships with those site study teams "on-the-ground."

CROs and sponsors should aim to engage more closely with sites, as they are carrying out the work and can provide valuable input. Most sites relish the opportunity to be more involved, offering insights on operational issues throughout a trial, which if used effectively can improve protocol development and assessment, as well as data quality.

There are several factors that can improve site relationships, including structured processes, consistent interaction and engagement, and purposeful communication.

Bringing Structure to the Relationship Process

Building and maintaining site relationships should be a structured process starting with early engagement with site leaders. A solicitation meeting should take place first, where a mutual confidential disclosure agreement (CDA) can be put in place, followed by a face-to-face meeting with the main study coordinators to agree upon lines of communication and potential pain points.

Next, high level processes need to be set for the following, to ensure collaboration at all levels:

- **Pre-award input:** how is the sponsor/CRO going to reach out to get a site's input on protocols, rather than just issuing a survey?
- **Site identification:** how will the site become one of the sponsor/CRO's preferred sites and vice versa?
- **Issue escalation:** how will this be handled without undercutting the CRA?
- **Communication:** frequency is key but should also be with purpose, so how will this be managed?

Consistent Sponsor/CRO Interaction & Engagement

Sponsors and CROs will benefit from working together when interacting with study sites, and should attend meetings together to forge and maintain relationships. Being proactive in engaging with sites can not only improve site commitment, but will avoid delays and accelerate the consultation process, speed up the start-up process, and result in higher quality outcomes.

For sites, fostering strong relationships with sponsors and CROs also has its benefits. Early, frequent engagement with protocol design and program development will result in a study which is easier for them to execute, and consequently, most sites will thrive off the opportunity to contribute throughout the study. Being involved in planning will mean sites know what to expect, and are aware of exactly what they should be looking for when it comes to patient recruitment.

It is also important for sponsors and CROs to seek advice from and collaborate with sites to develop clinical excellence. Sponsors and CROs can aid in understanding and create opportunities to share information with sites by reading articles, attending conferences, working with associations (such as the Center for Information and Study on Clinical Research and the Association of Clinical Research Professionals), and linking with relevant support and advocacy groups.

Communicate with Purpose

Today, relationships often are forged via email, Skype, etc., and while technology has clear benefits in terms of time and cost efficiencies, one cannot underestimate the value of building relationships via face-to-face communication. In addition to the importance of consistent communication, sponsors and CROs must also manage the frequency and quality of communication – you should be communicating with purpose. You should work to ensure that you are clear in all communication about any response that is needed or expected, as well as changes in processes, goals or timelines.

By communicating with purpose, engaging with sites throughout the study, and operating with clear processes, sponsors and CROs can make it easier for sites to conduct trials, enhance site commitment and improve data quality. To achieve this, investigator sites must be considered as true partners.