NEWSLETTER

Midsummer 2016

Five P's For A Productive Sponsor Relationship

For anyone in the position of managing clinical operations, few things are most important to develop a productive working relationship with Sponsors. A good site can bring your project in on time, meet all regulatory requirements, and do so with the level of quality Sponsor expects.
I spent many years within Pharma and CROs before starting own company and moving to the investigator side of the house. Tapping into the knowledge of different Sponsors that accumulated over the years, I would like to share five P's that every site manager should ponder if they want to get the most out of the clinical trial site.

1. Prepare, Prepare, Prepare.
Selecting the right site takes time and due diligence.
I feel sponsors should consider completing a three-step process when making their selection. Step 1 is talking to the site about Legal status, experience and capabilities. Step 2 is speaking with our actual investigator about project and patient pool needed. We are flexible to propose investigators team. We have on the list both experienced investigators and young doctors motivated and willing to learn. Step 3 involves physically visiting the Inlita site to see the professionalism of the staff the convenience, cleanliness of the facilities and equipment availability. An in-person visit can generally give you a good feel for the culture of quality that exists, which you can't get via a phone conversation or conference call.

KEY DATES

- First patient successfully enrolled on 25Th of May – two weeks after SIV.
- Inlita as a business enterprise has signed a cooperation agreement with academic Institution – The Lithuanian University of Health Sciences. Aim of this cooperation is to develop competencies in biomedical trials and creation of innovations.
- First 2 SIVs conducted synchronically in Inlita Lazdynu site and our partners site Northway Clinic on 11Th of May (sponsors Novartis and Biomapas).
- Second license for medical practice (Santaros clinical trial site) received on 11Th of April.
- CA accepted GCP trainings program for investigators on 8Th Ferbruary.

2. Plan For Everything.
Communication is the bedrock of a successful relationship with a site and this begins when Sponsor explains what assays needs to be performed.
Can the site meet all the regulatory criteria in protocol? Are you going to need samples assayed locally or stored in required conditions before sending to central lab? Are you going to collect digital data? Is it telecommunication connections? Is it archiving area available? We have answers for all these questions.
The basic plan for meetings would be to have an pre-study meeting to understand capabilities and services, a second more in-depth meeting with the investigators to discuss your specific project (Initiation meeting) once a Confidentiality Agreement is in place. Then periodic Monitoring visits (monthly or other depending on length and complexity) throughout the study.
I would recommend face-to-face meetings as often as possible, however technologies changing the word and one day SDV will be done remotely.

3. Point Of Contact.
Sponsor will be exchanging large amounts of information with the site, and this two-way relationship is most successful when you have an open line of communication with a person responsible for managing your project within the site. In our region Institution is not involved a lot. We are changing this approach: we have site manager and developing site coordinators position. It is important to transfer as maximum as possible administrative tasks from Investigators. And we do. Sponsor representative should be comfortable working with this Inlita person.

4. Pick A Time And Problem Solve.
Regular meetings (in person, by web conference, or over the phone) help keep everyone in the loop and can prevent problems from languishing for weeks. We would like to establish continuous communications so both you and we are always know where are with agreed targets and goals. One of success stories can be attempt to establish partnership with big state hospital. We conducted feasibility for new very complex protocol. Study team was completed, laboratory procedures agreed in a short period but contract with hospital was negotiated for 3 months. Finally projects failed. We started to look at possibilities to rent a doctor office nearby and now Inlita possess clinical trial site in the same building and few trials ongoing.

5. Don't Forget To Praise.
Finally, clients should not be reluctant to give praise when it is due. Good site invests significant time and capital into building high-quality operations staffed with experienced specialists. We also run our operations by using but not only displaying the highest standards of ethics, thus ensuring patient safety.
There is something to tell about Sponsors and other visitors satisfaction. As adapted patient history according each protocol. This enables our investigators to minimize potential mistakes or miss to collect required information for different patient visit. Our site in Santara valley is convenient for study team and patients and also simply but well designed.

Those added values will likely lead to a better and longer lasting relationship with Sponsors!

Sincerely, INLITA Founder,
Linas Liekis M.D.
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