



1. **How do you consistently beat study milestones?**
SC Liver Research Consortium holds master contracts with all 47 consortium sites, allowing you to contract with SCLRC as a single entity with a single budget. We'll offer you one or all of our sites (you decide) for your enrollment. Our study metrics prove we typically enroll two times faster than our competitors.
2. **How do you streamline the whole process?**
We keep site dossiers on all 47 sites with start-up regulatory documents for each Principal Investigator, as well as proof of human subject protection and hazardous materials shipping training. CROs or sponsors can get exactly what they need from 1 place. Having regulatory documents before the investigator meeting takes place, in addition to having all sites under master agreement and ready, has proven invaluable to our associates.
3. **If I enter into an agreement with SCLRC, am I committed to only using SCLRC sites for my trial?**
No. You can use all our sites, some of our sites or just a few. For example, if you had a partially enrolled trial with sites dropping out unexpectedly, you can make up the difference by getting SCLRC involved. Or, if you are behind and need to enroll quickly you can select all of our sites.
4. **Do you have a master agreement template?**
Yes. Once we begin a dialogue with a sponsor, with CDAs in place, we forward you an electronic version of our master agreement. Our master agreements, with regard to contract language (data ownership, confidentiality, publication, etc.), are basically the same from site to site; academic/medical center language. As long as the sponsor doesn't request drastic changes, the contracting process speeds along.
5. **How does the contracting process work?**
The consortium negotiates a single contract with the sponsor. We then team up and select the sites that will best meet your needs. With a contract in place, our Contracts Officer contacts the individual sites with protocol riders (protocol, budget and investigator disclosure). Remember, master agreements are already in place with all of our sites. Site negotiations can begin right away using this method. This has made it possible for sponsors to regain ground on a study that is falling behind or leap ahead with a new study.
6. **Do your sites have a different contract with SCLRC then we have with them?**
Some have minor differences but we can provide you with a copy. The differences in contracts usually occur over publishing and indemnification. Some sites want specific indemnification with the sponsor. We are flexible about customizing the protocol riders as long as the sponsor keeps in mind that our ability to promise and deliver results *with speed* depends upon the protocol rider not changing too much. The last two trials we launched beat enrollment milestones utilizing this method.
7. **Relationship with CROs?**
One of the reasons we work well with CROs is we do not compete with them. Since sponsors usually contact us in the early stages, we are asked to suggest or select a CRO. Once a CRO is in place, we meet in person or via teleconference and clarify the responsibilities for each party.
8. **Patient population availability?**
We'll query our investigators and patient databases and then provide you with an accurate representation of what we have to offer.
9. **How soon can you generate a proposal?**
As soon as we sign a CDA, receive the protocol, a timeline, and the number of our sites needed.
10. **Competing studies... if another company came to you with a similar drug, would you decline?**
If a new study proposal would compete with enrollment of an ongoing SCLRC study, we would turn the new proposal down. As you are aware, it reflects very poorly on an investigator if they have two studies competing for the same patient population. We frequently turn down similar studies. We are sensitive to this issue, as well as the issue of confidentiality.
11. **Non-performing sites?**
Sites in the consortium are handpicked based on their reputation for successfully performing research. Also, SCLRC routinely performs site visits and therefore has first-hand knowledge of their operation.
12. **Besides budget and contract help, what else can you provide?**
Some sponsors have asked us to hold the IND application (original submission packet, report SAEs and write the annual report). CROs also take advantage of the individual regulatory documents that we keep on file for each member of the consortium. They contact one person for reg docs versus twenty. Sponsors utilize us for site payments. Our highly motivated PIs provide quick enrollment which is always a bonus. Some sponsors use SCLRC to write protocols or improve them, especially if there is a critical flaw with the trial design. We can host advisory board meetings to guide a trial and we have recently entered the field of Continuing Medical Education with our Hepatitis & Infectious Disease Training Program series and our HCV monograph series which launched in 2004.
13. **Work with central labs?**
Yes. And we help sponsors establish relationships with labs by allowing us to be a liaison between the labs we already have a relationship with.
14. **What do previous companies have to say about working with SCLRC?**
"We have been impressed in our interactions with SCLRC's well-established network of focused investigators at key Hepatology centers, and it's ability to move our research forward with a tight focus." Stephen J. Mento, Ph.D., CEO of IDUN Pharmaceuticals