WORKING WITH CONTRACT RESEARCH ORGANIZATIONS

A CASE STUDY WITH CONTRACTORS

Preview Version

Part One

"This is the first out-sourced project that you have been asked to manage here at (Drugs –R- Us) DRU. It couldn't have come at a worse time, since you are overwhelmed with work. Several people recently left the department and have not yet been replaced. In addition, this isn't the only project you are working on. None of the others are being out-sourced, and they involve a great deal of work. However, you managed several projects at your former company and enjoyed the challenge.

DRU believes strongly in "partnering with the CRO", but your old company had a very different philosophy - - - the approach was very hands off. The assumption was that the CRO knew what it was supposed to do, the contract is clear, their staff is well trained, and their processes comply with regulations, - - - so just let them do it. You did meet quarterly with the CRO, but that was it, unless there were problems. "Don't micro-manage" was the usual instruction, and this is very much consistent with your own beliefs - - you really don't understand the DRU approach. This is also how you manage your own people - - - you give them an assignment and expect that the work will be done. If they have problems you expect them to come to you for help. When you lead teams your approach is no different. People are mature adults and if you treat them that way they will reciprocate. It's no different when working with CROs.

The project you will handle involves a new CNS compound, licensed in from a small Italian firm. This is their first compound and they have pretty much bet the company on this project. Enrollment is to be completed in two months, with a six-month treatment period. The entire project is to be completed by Clinical Magicians Inc. (CMI) in 13

months from the kickoff date. These are tight timelines and because of staff limitations, you have outsourced just about the entire project. (DRU will do the study report). Specifically, you have outsourced the monitoring, data management and analysis to CMI, the lab work to Omnipotent Research Laboratories (ORL), and automated patient randomization and clinical drug supplies management to IVRs. The total cost is 8.5 million dollars, which, while not large by most standards, is the largest project you have ever managed. The study will involve 30 multinational sites (10 each in the US, Western Europe, and Eastern Europe, each to enroll 20 patients for a total of 30 sites, and 600 patients)."

E Mail - From Liz

Original E-mail

Jack,

I just heard that Janet, the lead CRA on our project, left CMI to join another firm 3 weeks ago. This really troubles me since she was doing an excellent job and, if you remember, was their expert on Eastern Europe. If they don't replace her soon, we're going to have serious problems. I don't think they have anyone else with her experience. I haven't heard anything from CMI about who will be replacing her, and I think we need to say something to them. It's not wise to just leave this alone and treat it as if nothing has happened. Any thoughts as to what we should do? I am also concerned about the enrollment –Eastern Europe appears to be a problem. Only 5 sites were represented at the investigator's meeting, 2 couldn't come, and 3 still have not been selected. It appears that getting the remaining sites is not a big issue, but getting the sites up and running and recruiting the patients is clearly a problem. I didn't know how much of this is related to Janet's departure and how much is related to ethics committees' processes and delayed approvals. Recruitment is not going to be as easy as they suggested. Only 2 sites have even screened a handful of patients. I also heard from CMI that the central laboratory sample collection kits have not yet been sent to all of the European sites and the IVR's system has not triggered drug shipments to all of the sites that are ready for initiation. CMI is ready to enroll

patients at a number of the U.S. and Western Europe sites. Who should we have in the loop on this?

Liz

1st Reply to Liz-- E-mail

Liz,

I agree, (Janet's departure) doesn't sound good. Why don't you follow up with them and get back to me? I will also get in contact with Ed at CMI and see what is happening. Were we supposed to get some kind of confirmation on the shipping of the sample collection kits? I'm not sure about the drug supply issue. Any thoughts who we should specifically contact at IVRs?

Jack

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E Mail -From Liz

Original E-Mail

Jack,

I am not sure if you heard, but CMI has hired Barbara Freitag to replace Janet. I worked with her only once years ago, and while she was an excellent CRA, I didn't remember her as being a very good manager. And I have no idea what her Eastern Europe experience is!

I think we should ask to meet with her to determine if she is right for our project. This really troubles me. At a minimum we should have been allowed to approve her before she was assigned to the project. This isn't the way we do business and they know that.

Liz

Jacks Reply ----E-Mail

Liz,

They feel very comfortable with her, as do I. I spoke with her on the phone during their interview process and reviewed her CV and I think we need to go with their choice. This isn't something they did without consulting me; a decision needed to be made and you were away. Anyway, she's already on board and I don't see what we can do at this point.

I am sure it will all work out. They know how important this project is to us.

Jack

2nd Reply E-mail

Jack,

I know I was out of the country for an extended period, but I feel strongly you should have involved me or one of my people in this decision.

Liz

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Part Two

"You just returned from a ten-day vacation. At the insistence of your spouse, neither of you took computers. This was to be a vacation with the children, with no work. It was a great vacation. However, after reviewing all your e-mails, it's clear that the problems on the CMI study are even more severe than you anticipated. While you were away, your secretary forwarded all project specific e-mails to Liz. You and Liz spoke before you left and agreed that she would handle whatever came up. You also spoke with Ed to let him know that you would be away and that Liz would be covering for you. Most of what transpired was minor, but one of Ed's memos really troubled you. It came the day after you left and focused on patient enrollment. To quote him, "*We continue to have enrollment problems at several of the sites, but nothing we can't remedy over the next several weeks*. *Most of the problems are in Eastern Europe, but several of the US and Western Europe sites seem to be struggling as well. We have finally been able to recruit all the sites but the time to initiate each site and get them up and running is proving to be a real problem."* He continues "*We are doing much better with the U.S. sites, having achieved the target enrollment. However, in Western Europe, drug deliveries were delayed and this has impacted their enrollment activity, but it is accelerating. The very late initiations (due to slower than expected site recruitment, late drug supply and late sample kits) in Eastern Europe have made it impossible to achieve the target enrollment in the designated timeline. The remaining Eastern European sites*

that we plan to initiate continue to have delays in collecting regulatory documents. We may miss some of the ethics committee meeting dates. "

- Just yesterday, another e-mail from Ed with an update on the enrollment indicating that, "*Enrollment continues to be a problem. It is very likely that we will need to recruit additional sites. The current sites just are not going to be able to meet our needs.*" He goes on to say, "*In addition, we continue to have problems communicating with ORL's staff and with your people. We ask for information and while it eventually arrives it is too late. This is hampering our ability to move ahead as quickly as we would all like. We are also now learning that some of the sample kits are not being received in time from the sites for analysis and some of the lab data will either not be available or valid*

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You expected that patient enrollment would be around 200 per month. The latest total is 390 patients, down by more than 30%.

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Note: The complete case is twenty – one pages in length. In addition to the narrative illustrated above we have also included three and six month enrollment data. A trainer guide for the case study is also included in the package along with additional exercises and two practice negotiations.