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Clinical Research Bullies

By Norman M. Goldfarb

When the stronger party in a relationship threatens or intimidates the weaker party, the weaker party perceives the behavior as bullying. In general, research sites see themselves as the weaker party in the sponsor/site relationship. Interestingly, because sites can jeopardize a clinical study by stopping enrollment or embargoing data, sponsors often see themselves as the weaker party in the same relationships.

Depending on the circumstances, sponsors, sites and contract research organizations (CROs) can all bully each other. Key opinion leaders at sites can bully sponsors and CROs. Large companies can bully small companies. Experienced people can bully inexperienced people. In the examples below, sponsors are bullying sites, but the discussion is applicable to bullying in any direction.

Threats can be explicit, implied or implicit, for example:

- "Correct this problem or we will terminate the study."
- "Correct this problem or I don't know how we can work together."
- "Correct this problem and then we can decide how to proceed."

Context and tone are important in evaluating what appears to be bullying behavior. Hostile or abusive language is inherently threatening because it indicates that the relationship is damaged beyond repair, with serious consequences likely. Some statements, such as "Let's not get the lawyers involved," are easy to misconstrue no matter how carefully they are positioned.

Bullying may effectively intimidate the other party with no apparent negative consequences. However, there may be subtle but serious effects. For example, a study coordinator may falsify data rather than risk the stress of future bullying.

Bullies present themselves as more powerful than their victims, based on a difference in the size of the organizations, job titles, or status of the parties involved. They may overstate their ability to carry through with their threats. Bullies often present themselves as more expert than their victims. For example, they may speak with confidence of nonexistent regulatory requirements and unlikely consequences.

Examples of Bullying Behavior by Sponsors

Sponsors bully sites when they threaten consequences that are excessive to the situation, for example:

- Complaining about the study coordinator to the principal investigator
- Terminating the study at the site
- Blackballing site for future studies
- Reporting the site to the IRB and/or FDA

The following are real-life incidents of behaviors that experienced sites perceived as bullying. Of course, the sponsors involved probably have different perspectives on the incidents.

Site A conducted a study for a large pharmaceutical company. It sent one subject to a local lab for a difficult blood draw, with documentation in a note to file. Eighteen months later,

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the monitor instructed the site to add the local lab to the 1572. The site refused, based on advice from its IRB and the FDA. The sponsor's clinical director threatened to terminate participation by 80 active subjects and withhold payment.

Resolution: The site requested the instruction in writing. The sponsor complied. The site added the local lab to the 1572. The sponsor has not invited the site to participate in further studies.

Site B enrolled three subjects in a study for a large pharmaceutical company. An independent monitor spent four days per week at the site for six weeks. The monitor had the coordinator change and re-change data back and forth several times and then called in a colleague to assist with the "terrible mess." The site manager complained to the monitor. The monitor threatened to tell other local CRAs about what a disaster the site was.

Resolution: The site complied with the monitor's instructions. It did not complain to the sponsor, for fear of retaliation by the monitor. The sponsor has not invited the site to participate in further studies.

Site C conducted a study for a large pharmaceutical company. The monitor behaved in a professional manner with the investigator and site manager, but spoke to study personnel in an abusive, demeaning and threatening manner, including racial slurs. The site manager met with the monitor to correct the situation. When the situation did not improve, the site manager complained to the project manager. The project manager denied that the monitor could have behaved in such a manner and would not replace the monitor at the site. The monitor returned to the site and threatened to get the coordinator fired by telling the investigator that the coordinator was uncooperative, calling the coordinator "a stupid [racial epithet]." Two witnesses, including the site manager, overheard these statements. The site manager told the monitor to leave the premises. The monitor returned the next day and refused to leave until the site manager threatened to call the police. The sponsor investigated and concluded that the site's complaints were unjustified, but replaced the monitor. The site later investigated and informed the sponsor that the monitor had engaged in similar behavior at other sites.

Resolution: The sponsor has not invited the site to participate in further studies.

Site D conducted a study for a medium-sized pharmaceutical company. On a Friday afternoon, a family member notified the site that a subject had been hospitalized. The site submitted a serious adverse event (SAE) report to the sponsor later that afternoon. Because of missing and unreliable information from the family member, the SAE report did not include a diagnosis or assessment of causality. The sponsor's safety officer called the study coordinator and instructed him/her to assess causality on the report, saying it is an FDA requirement even on initial reports, and threatened to report the investigator to the FDA if the study coordinator did not check the "not related" box for causality. The site manager then got involved and informed the safety officer that causality could not be assessed without further information and medical records review, and then only with the investigator's authorization. The safety officer backed down.

Resolution: The safety officer stated that he/she wanted to avoid having to stay late on Friday to file a MedWatch report and that without a causality statement, he/she would be forced to do so. The site assessed causality in the follow-up SAE report. The sponsor has not invited the site to participate in further studies.

Site E conducted a Phase I study of a skin patch to administer an approved drug for a small pharmaceutical company. Several of the healthy-normal subjects had to be withdrawn due to adverse skin reactions. The sponsor asked the site to change the withdrawal reason from "withdrawn due to adverse event" to "withdrew consent." The sponsor's rationale was that, since the subjects were not in the "intent to treat" population, it wanted to keep the data

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out of the record. The site refused, even after the sponsor threatened to close enrollment at the site.

Resolution: Pending

Site F signed a contract to conduct a study for a large pharmaceutical company. The site completed the regulatory package and submitted it to the central IRB, which approved the site. The sponsor then put the study on hold. The site invoiced the sponsor for the contracted start-up fees. The medical monitor called the site and, in a raised voice, stated that the fee was too much and instructed the site to send a breakdown of the fee for review. The site did so. The site did not hear back from the medical monitor. Three months later, the sponsor put the study on hold indefinitely. The site resubmitted the invoice by email. Within minutes, the medical monitor called and, in a loud and hostile voice, said the site would never work with the company again if it insisted on payment. The site reminded the medical monitor that it had paid salaries to do the work months before for the contracted fee. After the site told the medical monitor that it felt threatened, his/her tone moderated, but the call ended without resolution.

Resolution: The site called its agreement/budget contact at the sponsor, discussed the situation, and received payment three months later. The sponsor has not invited the site to participate in further studies.

Recommendations

Bullying behavior is likely to interfere with constructive problem solving and damage or destroy relationships. The following recommendations may be useful to both sponsors and sites:

- Think twice before making any statement that may be perceived as bullying. Constructive communications are more likely to yield positive results.
- Bullying may appear when the person's patience with more productive methods has been exhausted. If you are being bullied, consider this possibility and say something like, "We are all frustrated here. Let's see if we can work through this problem together."
- If your people are frustrated, stressed or exhausted for any reason, watch for bullying behavior.
- Bullies often bluster, hoping shock and awe will compensate for lack of substance. If you think you are being bullied, slow the discussion down. The bully may just run out of steam. Ask the bully to clarify what he or she is saying. The bully may have a good point or perhaps just a forceful personality. Ask the bully to provide instructions, details, such as regulatory citations, and consequences in writing. Involve supervisors, especially if they have more expertise and experience.
- Take complaints and indications of bullying seriously, especially if the other party is not prone to whining (a different behavioral problem). Note that some people interact differently with different categories of people, e.g., supervisors vs. subordinates. Bullies tend to repeat the behavior, so investigation may be revealing.
- Try to prevent conflicts from escalating into battles that are more about winning than constructive solutions.
- Role playing with audio or video recording is an effective method of training.

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