JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 8, No. 4, April 2012 "Happy Trials to You"

Steve Jobs, CRA: What Would Steve Do?

By Eric Ceh

Steve Jobs, through Apple Computer, has literally touched our lives.[1] His leadership of Apple Computer was so strong that many employees adopted a simple decision model: "What would Steve do?" But what if Steve Jobs had, instead, been a clinical research associate (CRA)? As a CRA (site monitor), what would Steve do?

Steve was beyond fanatical about quality. Anything less than perfection was unacceptable. And he expected everyone to take personal responsibility for quality without compromise. Before travelling to initiate his first site for Apple Pharma, he would read the protocol with great care. He might get as far as the second page before reaching the inevitable conclusion: "This is shit." He would cancel his trip, study the protocol in detail, interrogate everyone in sight, revise the protocol from beginning to end, march into the study manager's office, slap the new protocol on her desk, and passionately announce, "Here is the insanely great protocol we are going to use." Steve's reality distortion field would be at full power.

Before the project manager had a chance to say a word, Steve would convince her that the most important clinical study in a decade was within their grasp. He would persuade her to quit her job if her boss was so idiotic as to disagree. Within 24 hours, all of the investigators and study coordinators would have a copy of the protocol with strict instructions to comment within 24 hours. Within another 48 hours the new protocol would be fully approved by the company. Within another 24 hours, the IRB would have convened a special meeting to approve it, Steve would have retrained all the other CRAs in a video conference, and all his sites would have committed to do their best work ever or never hear from Apple Pharma again. Steve would somehow arrange a meeting with the FDA by the end of the week to obtain its blessing and probably its agreement to pilot a new process for real-time oversight of the study.

Steve would be at his first site at 8:55 AM Monday morning. The site initiation meeting would begin at 9 AM, with all study personnel, including the investigator, in attendance. If the study team does not share Steve's passion for the study by 10 AM, he'd be gone. If they do not demonstrate their competence (or willingness to learn, and quickly) by 11 AM, he'd be gone. If they do not have a list of potential subjects by 3 PM to start calling that evening, he'd be gone. If they have not agreed by 4 PM to address any weaknesses in the site's quality management system, he'd be gone.

Steve's manager might hear from an investigator who had been handled roughly by Steve. The manager might share her concerns with Steve, but we already know what he would say: "We can't work with a shit site. Find me one that's good enough for our study."

It would not take long before "Steve's study" dominated hallway conversations at Apple Pharma. Steve's gravitational field would start sucking in the best people and resources to ensure high-quality, on-schedule execution.

Don't expect Steve to stick to tried and true conventions. The compliance office would soon be fielding questions like, "Under the Sunshine Act, do we report the retail price, the wholesale price, or the manufacturing cost of the iPads Steve gave his sites?"

Steve would arrive at monitoring visits fully prepared, and would expect the same from site personnel. Heaven help the study coordinator who had not entered all his data or the investigator with an unsigned lab report on his desk. But, it would seldom be a problem

because they would understand Steve's high standards and share his belief in their importance. They would know that if they do their job, he would support them 100%. If there were a problem, Steve would know the pertinent sections of the protocol, clinical trial agreement, regulations, guidances and his own directives. He would accept no excuses, or maybe once if performance had otherwise been exemplary. Of course, the investigator could go over Steve's head to ask the project manager for a bit of slack, but how likely is that to work?

Steve would, no doubt, show up in a long-sleeve black shirt, black jeans, and perhaps sandals. He would work intensely, perhaps eating some fruit for lunch. He would schedule brief, periodic meetings with the study coordinator and expect expeditious answers to any questions that arise. Most open issues would not be open by the end of the day. Nobody would mistake Steve's monitoring visit for a social call. His, shall we say, bluntness would take some getting used to, and there might be tears.

Steve's visit reports would be cogent, concise, brutally honest, and in the project manager's hands by the next morning. If he were to grade the sites, they would all get either an A or an F. In Steve's world, there are only geniuses and morons.

Steve's head would likely explode if he tried to be a CRA. Even someone as forceful as Steve probably could not single-handedly change a culture that so readily accepts endemic mediocrity and even failure. Steve could not survive in a culture where achieving perfection is beyond imagining. Sure, clinical research is hard, with unending challenges and complications, but is it that much harder than reinventing entire industries? Perhaps it is time to examine how we do things and ask, "What would Steve do?" Perfection may be out of reach, but we should be able to get a lot closer.

Conclusion

Perhaps, because of their clinical load and the fact that they practice medicine on a daily basis, it would be difficult for many sites to obtain the degree of perfectionism that SJ would demand. Seasoned CRAs, although meticulous in their approach, understand the realities of the clinical environment. Some, more than others, have a passion and attention to detail that SJ would be proud of.

Reference

1. *Steve Jobs* by Walter Isaacson, Simon & Schuster, 2011.

Author

Eric Ceh is President of SEC Clinical Consulting, a provider of monitoring, quality assurance, and project management services. Contact him at 1.614.823.7937 or sec_consulting@sbcglobal.net.

