



aktaPD: an Action-oriented Approach to Pharmaceutical Development

aktaPDology: 5 Tips for Smart Clinical Operations

No one—neither prophet, nor king, nor God—can convince 1000 cats to do the same thing at the same time.
—Neil Gaiman

But, that's just what a savvy clinical operations professional does, day in, day out. Clinical Operations is all about attending to the thousands of details and, often, hundreds of people (usually scattered around the world) working to move a product successfully through the drug development pipeline. It's a balancing act that rivals a tightrope walker juggling machetes while riding a bike across the thin wire connecting two towering skyscrapers...blindfolded: it's all about keeping a lot of balls in the air, making sure all the parts move smoothly, finding and repairing holes in the process, and moving heaven and earth to meet the client's timelines and budget. Most important of all, according to Lynn Sutton, aktaPD clinical operations consultant and a respected speaker and thought leader with 25 years of insight and best practices for accelerating results, it's a process that affects lives—both the product's and patients'.

"There's often a huge disconnect between the business objective of getting a compound or device approved—running the successful study, getting it through regulatory, doing the marketing and sales—and recognizing that attached to all those numbers to prove efficacy and drive statistics is a human life," she says. "A seasoned clinical operations team assures trials are flawlessly executed according to the stringent and complex regulations of FDA and worldwide agencies to protect those subjects. It's our job to drive the client's business objective, coming up with strategies to help ensure timely execution of clinical trials and leveraging opportunities to buy back or save time and maximize efficiencies, all while not compromising the safety of the patients participating in the study. It's a big responsibility. That's why it's so important to get it right."

The surefire way to find a needle in a haystack? Take a deep breath...and sit down.

aktaPD has experience with haystacks. All of our experts have sat on both sides of the table, having worked from the sponsor (pharmaceutical company) and the physician perspective. It takes expertise from both sides of this equation to add value to clients planning their next clinical trial.



