



*Stay late and bring snacks: Nine steps running more successful clinical trials for acute conditions*

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By: Rachel McCorkle | June 15, 2015

Enrollment planning is always a challenging aspect of a clinical trial, but, for acute conditions, like COPD exacerbations, acute thrombosis, or the flu, the challenge of recruitment planning is even more difficult. One of the biggest challenges in recruiting patients for these trials is connecting with them at the right point in their care to make them relevant candidates for the research. There is a narrow window for enrollment, and acute care patients enter the healthcare systems at a variety of touch points making it difficult to catch them at exactly the right moment in their care journey. If researchers can't figure out when and where to engage with these patients, they will miss opportunities to recruit them into their trials.

In my DIA presentation this year, I shared a number of best practices that have helped us improve the speed, efficacy and retention of our recruiting efforts for clinical trials in acute conditions. Here are my favorites.

- **Stay open during off hours.** We have discovered that one of the most successful recruiting and retention strategies for these trials is to simply stay open late, and on the weekends. These patients present with the condition under study at the most unpredictable of times which has the high possibility of not being during normal business hours. By staying open during off hours, you are able to capture these patients in real time and eliminate one of the biggest barriers to participation – unpredictability. This one change can have a tremendous impact on results: in one study, we set a goal of recruiting six patients and ended up with 76. Our research showed that one-fourth of them enrolled over holidays and weekends. Note: Make sure you enact a buddy system for coordinators seeing patients outside of regular hours to ensure there is more than one employee on site when patients are seen.
- **Choose sites that offer multiple specialties.** The diversity of services offering at these sites will enable you to provide a one-stop shop for all procedures and tests, which is more convenient for patients, creates easier management of patient data, and reduces the risk of patient attrition to other facilities.

- **Choose sites with a past history of success with such trials.** Select sites based on thorough evaluation of previous enrollment on acute studies not necessarily studies of same indication. When considering a site, ask about any creative or innovative recruitment methods. A site that can speak to this history with enthusiasm is a site with a good chance of success.
- **Consider running the trial as a non-inpatient study.** In-patient studies are complicated, expensive for researchers, and potentially burdensome for patients. When designing your trial protocol, determine whether your trial requires a fully in-patient environment or whether some or all of it can be conducted in an out-patient setting. Naturally, this will vary based on condition, but this option should be considered when possible.
- **Engage investigators in the recruiting process.** They are the ones who understand the intricacies of the research, and are best positioned to engage patients in discussions about their disease, and to understand the inclusion/exclusion criteria governing who should participate.
- **Conduct mock screenings to hone your program plan.** When you are targeting a small patient population in a limited timeframe, you don't want risk losing suitable candidates due to mistakes made during recruiting. Running a mock screen, that includes every step from identifying the "patient", to running through the entire recruiting process, including paperwork, interviews, and preliminary labs, will help you clear bottlenecks, streamline your order of operations, and identify risks that could cause patients to drop out.
- **Establish strong relationships with local physicians, nurses, and ER staff.** In most cases, the only way you are going to find the right patients is if the treating physician or caregiver introduces them to you. So the best recruiting strategy is to educate all of the local care givers about your trial, including your timeframe, the specific types of patients you are looking for, and how they might talk to patients about participating. Patients can turn up in a variety of care settings, so make sure you expand your network to all possible destinations.
- **Make it easy.** When you build relationships with local care providers, don't overburden them with extra steps, or too much information about your research. If you want them to send

patients your way, make it as easy as possible. Ideally all they should have to do is make one phone call to let you know they found a possible patient, and you should take care of everything else.

- **Be nice to the support staff.** When conducting a trial in a hospital or other care setting, the people doing your lab work or other particular clinical procedures are typically not going to be your direct reports. They are busy clinical staff who may be a little resentful at having to do your extra work. If you want speedy results, you need these people to like you. So remember to say please and thank you, bring them small treats, and let their superiors know what a good job they are doing. Kind gestures can go a long way in winning their support.

**Topics in this blog post:** [Biopharma](#), [Clinical Trials](#), [Recruiting](#)

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