Three Questions

Mohammad A. Millwala, DM Clinical Research

CWWeekly *presents this feature as a spotlight on issues faced by executives in clinical research. This week, writer Karyn Korieth spoke with Mohammad A. Millwala, CEO of DM Clinical Research, a network of investigative sites based out of Tomball, Texas. DM Clinical Research was a finalist for the Society for Clinical Research Sites' 2016 Site Patient Recruitment Innovation Award (SPRIA), which recognizes research sites that have developed and implemented innovative patient recruitment programs.*

Q DM Clinical Research was recognized for its successful recruitment program for a respiratory syncytial virus (RSV) vaccine trial that required the site to recruit relatively healthy adults aged 60 and older, with one-fourth of volunteers aged 76 and older. What was your strategy?

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Mohammad A. Millwala, CEO, DM Clinical Research

A Educating the local community and patients about the virus and the benefits of the vaccine was crucial. We conducted an open house to kick off the recruitment. With the help of our local chamber, we invited the citizens of Tomball and the surrounding area to our site and had a previous research participant, who was a veteran, describe her experience in research at our site and the importance of this RSV study.

We also handed out IRB-approved flyers at bingo centers, the Veterans of Foreign War center, walk-in clinics, churches, nursing homes and local restaurants that were popular with the elderly. The outreach helped not just for this particular project, but also increased knowledge about research in the community. Many people, especially the elderly, are nervous about trying something new. Our principal investigator (PI) trained our coordinators and recruiters about RSV and how to answer questions about research.

We strongly feel that we don't just want to enroll patients. We want to first educate them and make sure they understand what we are trying to do. The sponsor goal was enrollment of 190 subjects per site. We screened 267 patients and randomized 254 patients in 23 days. One patient passed away and three terminated early, but we finished with the other 250. When patients are educated and are part of the process, retention becomes easier.

The site is within a family practice clinic and about 90% of our participants came from the site research and clinic databases. We didn't use any outside advertising other than community outreach. Our PI, Earl Martin, D.O., was highly involved with the recruitment process. The PI and two sub-investigators spoke to every single potential patient identified in the clinic about the study. Dr. Martin wanted to ensure that the potential participants had enough time to understand the study and that he was available to answer any and all questions. He blocked off his calendar for 17 days and did not see any clinic patients during that time. He just did research. He opened early and stayed late so that patients could walk in, even if they didn't have an appointment, and we would accommodate them. He ended up being involved in consenting 100% of the patients randomized.

One obstacle was that our recruitment funnel attrition rate was higher than expected. Our initial target of pre-screening 400 patients on the phone didn't prove to be enough. We started losing more than 50% of the patients when we called them back for the screening visit. We immediately re-aligned to start calling more patients in our database. Being proactive and agile was critical to meet and then exceed sponsor enrollment expectations. We also felt that creating a buzz in the clinic would help motivate staff and foster awareness among patients. Staff wore tee shirts and buttons that said things like, "Ask Me About Research."

Q Was there a specific aspect of the campaign that was most important to its success?

A We tried to create a great experience for volunteers. We wanted to give concierge service to the patients.

We identified and dedicated one person as a patient advocate. She was an active part of the Tomball community and her job was to ensure that the patient would receive 360-degree care, which we defined as caring for the patient from pre-screening through the last study visit. From the moment potential subjects came to the clinic, they were given VIP treatment. The patient advocate was phenomenal in talking to patients and making sure their needs were met. She checked on patients during their visits and made sure they understood what happened and what would be expected next time. She was at the center of the entire patient interaction.

The extra attention patients received from the doctor and patient advocate resulted in 27 study subjects being referred to us by existing patients and helped with retention.

Q What could other sites learn from your experience in recruiting patients for the RSV vaccine study?

A We should treat our patients with a lot of respect, regardless of their social or economic background. Respect carries a lot of weight. Sometimes in the rigmarole of our busy days, our staff might forget to say hello or forget that the patient has been sitting for 45 minutes in the waiting room. Those kinds of things cannot be overlooked. A good refresher course on customer service could go a long way. Clinical trial participation is not compulsory for the patient. They want to volunteer for a good cause, so we need to show them appreciation.