

The Pulse on Recruitment By Cara Danchak

Because the healthcare industry views diseases from a clinical perspective, they may not always recognize the sensitivity involved with discussing certain conditions and/or symptoms with non-medical professionals. However, when preparing a **clinical trial patient recruitment** campaign for “sensitive” conditions, such as erectile dysfunction or genital warts, sponsors must keep in mind that the media could be your best friend—or your worst nightmare.

Non-subscription-based media (such as broadcast television and local radio) can take an aggressive stance aiming to protect audiences from what some viewers/listeners might consider inappropriate content: the discussion of some symptoms. Audiences generally expect daytime programming to come with a “G” or “PG” rating. But to be consistent with our “direct response” media strategy, daytime programming is necessary. So a solution for how to handle “sensitive” content and still meet the media’s ethical standards is imperative.

A perfect example of how this affects our industry is a 2010 project with our client, TKL Research, which was working on a “sensitive” study. TKL, an international **CRO**, was working with the women’s health division of a major pharmaceutical company on a **phase II bacterial**

vaginosis (BV) study. The sponsor had the same hopes as most—to reduce the enrollment timeline while staying within budget.


In the first conversations between Clinical Trial Media and TKL, it became clear the creative message was going to be critical to the success of this study’s timeline. TKL provided an in-depth assessment of the potential subject population, highlighting that most women were misdiagnosing themselves as having a yeast infection, not BV, and were potentially self-treating incorrectly. TKL, based on past history of successfully using descriptive symptomatology language, wanted to explore the risk of including symptoms in the ad copy with the hope of stimulating a significantly higher number of women who had been misdiagnosing their BV to call for more information. CTM agreed with the strategy. However, BV symptoms include a grayish white or yellow vaginal discharge and a “fishy” odor—terms we instinctively knew would not be acceptable to many radio and TV stations.

A quick decision had to be made. The sponsor wanted ads created and submitted to the IRB within two weeks because it wanted to beat anticipated enrollment goals. However, CTM felt it was too risky to develop ads without input from the media. What if we went through all of the rounds of approvals

and production, only to have the media turn the ad away? This would result in considerable time lost in moving toward our enrollment goals.

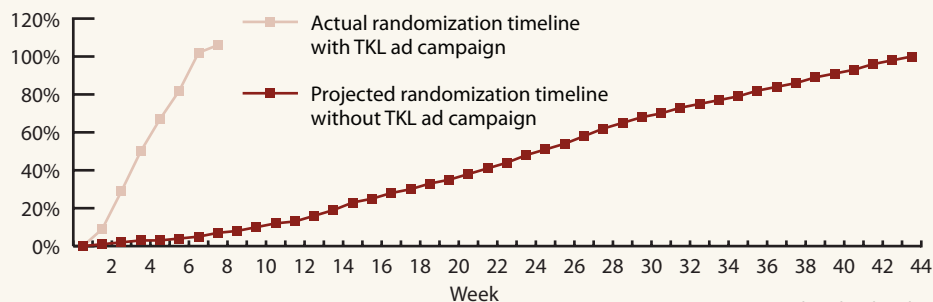
Instead, CTM and TKL agreed to develop two versions of draft ad copy—one citing BV symptoms and one without—and submit them to various stations for “pre-approval.” From there, we would be able to revise our ads to achieve the necessary sensitivity prior to IRB submission.

As anticipated, many stations had an issue with including the words “vaginal discharge” or “unpleasant odor” in daytime commercials. Confident in our decision to have options, CTM and TKL worked together to prepare two sets of ad materials, which TKL then submitted to the IRB. Once approved, we began to place local advertising schedules with the media and first submitted only the ads that included symptoms. As expected, approximately 70% of stations did not accept them. Prepared with our back-up ads, we submitted the second set of ad materials that did not include symptoms. All stations accepted the softer ads. Most important was the outcome: Despite the non-mention of symptoms, ad response was fantastic. In fact, TKL dramatically reduced the sponsors’ original projected timeline by 85%, enrolling the full study in just seven weeks, 37 weeks ahead of schedule.

Having two experts on your side can help foresee advertising issues before they happen. Imagine the delays that would have resulted had we created only one set of ads. Sponsors need to trust their vendors. Although altering our start-up strategy caused a slight delay, TKL and CTM recognized that this change would only improve the study’s chance for overall success, not hinder it. And in this case, thankfully, the sponsor agreed. 

Multi-center bacterial vaginosis study Projected enrollment without TKL support vs. actual

With TKL’s managed advertising campaign, 106% of patients were randomized in seven weeks, reducing the recruitment timeline by 85%.



Source: Clinical Trial Media

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