

Fifty shades of hay

Hunting for qualified clinical research subjects can be like finding the proverbial needle in the haystack. Until, that is, you find where the needed haystacks are. That's where *Fifty Shades of Grey* comes in. **Sandra Shpilberg** explains her successful online approach

Fifty Shades of Grey: I never expected to utter this phrase in my role at Nora Therapeutics, and yet I found myself repeating it about 10 times a day for the past few months—not at the water cooler, but in my office, and within the context of serious strategic discussions on how to help patients learn about our ongoing clinical trial. This phrase, it turns out, was partially responsible for shaving six months off our trial enrollment projections.

Let's start at the beginning. In late 2014 our small company, Nora Therapeutics, set out to enroll patients in our Phase-II RESPONSE trial to test a new potential therapy for women with unexplained recurrent miscarriage. Despite significant unmet need, there are no FDA- or EMA-approved medicines to treat this condition. With little industry precedent, our clinical team worked diligently to identify the best sites and physi-

cians in the United Kingdom with whom we could partner to identify, educate, screen and enroll patients.

While the sites indeed enrolled many qualified patients, we still were at risk of falling behind and needed an additional cost-effective strategy to meet our aggressive study timelines. Intuitively, we understood the situation at the clinical sites: Patients don't engage with healthcare providers as frequently as they interact with their friends, smartphones and computers. In knowing this, we made a strategic decision to launch a robust campaign to enable patients to connect to us where they were spending much of their time—online. We thought of this strategy as a funnel and our job was to sift through potential online study participants, or "leads." Along the way we crafted and refined each of these five steps:

1. Define the Audience

We began by selecting a highly targeted audience for Google Ads and Facebook, thinking that in order to find needles in a haystack, we should first look in needled haystacks. Thus, we first displayed our ads to women who had already defined their interest in the topic of miscarriage (for instance, through Facebook groups they had joined or through their search patterns). While this initial approach was under way, we wondered whether there were additional women who had not necessarily self-identified themselves but who nonetheless might be interested in learning about our trial. To reach this larger group, we used the Audience Insights tool on Facebook and our intuition to find shared interests, one of which was *Fifty Shades of Grey*.

2. Deliver Impressions

Prior to delivering impressions, we submitted our proposed ads to the ethics committee (EC) for approval. The language is careful not to promote any claims about our investigational treatment. As we delivered impres-

sions of our ads to our audiences, we learned that the more targeted our ad, the more effective it became in finding cost-effective leads. Our best-performing ad was clear and specific, calling for women who have had three or more miscarriages (see below).



Sample of our most specific and effective ad on Facebook, previously approved by the ethics committee.

3. Drive Clicks to the Website

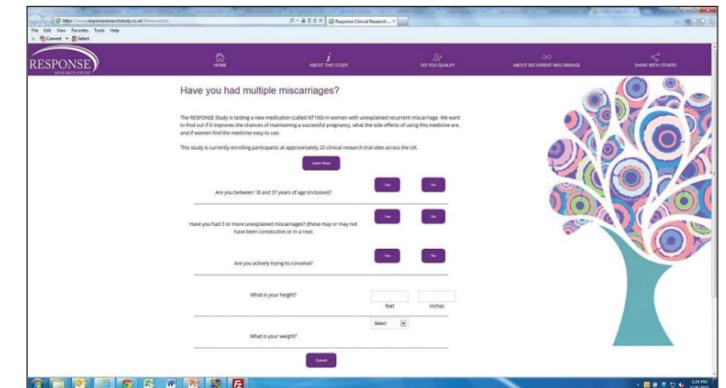
Our "Learn More" button took users to our website and gave us data that helped us analyze when, where and how our audience was clicking on our ads. Our analysis showed us that 80% of our clicks were coming from mobile phones. Though our initial website had been optimized for desktops, we quickly invested in mobile optimization to ensure our site could receive leads via phones.

4. Use the Website to Prescreen

We initially selected two questions for the online screener and were inundated with leads. Our sites shared their appreciation but also their frustration because several leads didn't meet the rest of the inclusion criteria. Thus we added two additional questions to the web screener. Leads still poured in, but now we had saved the clinics hours of work screening leads that would never turn into enrolled patients.

5. Send Leads to Clinics and Follow Up

Our clinical operations team continued to engage with the clinics to encourage and track follow-up on the leads. At all points we ensured the privacy of the patient information collected, which was protected and



The RESPONSE Web Screener

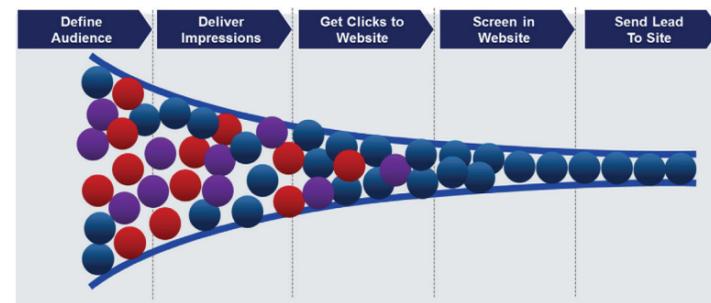
only shared for the purpose of facilitating screening into the study.

Our online efforts have been instrumental in enrolling our trial to exceed our aggressive goals, enrolling six months faster than projected prior to the start of the campaign. These efforts were also formative in driving our strategy and goals: Our role is to intersect patients in their natural habitat with relevant and specific information on which they can act now. The patient we may need—for our study or to try a new approved product—may be at the clinic for 20 minutes once a year, but she is on Facebook, on her smartphone and on her computer every day. We should meet the patients with information they can act upon exactly where they are—online.

Innovative tools like Apple's ResearchKit can take this approach even further. Until now, taking part in a medical study has usually required traveling to a clinic to complete data collection. With ResearchKit, a patient uses his or her iPhone to sign the informed consent and generate data wherever they are. Though these apps are not yet ready to accommodate the complexities of investigational drug development trials, they do provide massive reach, convenience and scale for supportive studies on patient-reported outcomes. But apps don't find themselves and thus the study sponsor continues to have a key role in helping patients find the app from ResearchKit.

At the end of the day, helping ourselves to be found becomes the key competitive advantage for any drug developer.

Sandra Shpilberg is VP, strategic marketing and commercial planning, Nora Therapeutics, Inc.



The Funnel for Finding Patients Online