

Using a Web site strategy to develop and implement a worldwide recruitment program.

# Global Subject Recruitment

Melynda Geurts and Lacey Blowers

**G**lobal patient recruitment today requires a multilayered, multifaceted approach to bring to fruition the most effective outcomes within predicted recruitment timelines. This approach requires constant monitoring and updating of regulatory implications, customs, and guidelines in all areas of practice.

Here we specifically focus on the many challenges and opportunities presented when using study-specific Web sites as a global recruitment strategy.

Study-specific subject recruitment sites are growing in popularity, with 68,458 clinical trials listed with the National Institutes of Health (NIH) in 2009. The PEW Internet Health Study<sup>1</sup> reports the following:

- Eight in 10 Internet users go online for health information
- 113 million consumers have searched for health and wellness information
- 73% of chronic disease sufferers searched the Internet on their disease
- 75% found information that affected their decisions related to treatment
- 69% asked their physician questions and/or sought a second opinion

This heavy reliance on the Internet mirrors the boom in Web browsing for health information globally. With increasing Internet penetration, online recruitment offers broad geographical reach, an educational platform for patients, and cost savings over more expensive forms of advertising.

## Web Strategy Challenges

Web initiatives are fairly straightforward in the US, primarily due to the fact that most sponsors' privacy policies and regulatory guidelines cover users based in the US.

In contrast, as an international strategy, using the Web can prove to be more time consuming and costly because of the shift in the audience.

For example, in a recent project where 10 countries were proposed for Web initiatives, only two countries were mobilized. Countries initially proposed included India, the United Kingdom, Spain, France, Germany, the United States, Mexico, Switzerland, and Belgium. Only the programs in India and the United States received approvals within reasonable timelines.

Other significant challenges for a Web-based strategy may include:

- Version control
- Cost implications
- Privacy policies
- Ethics committee rulings
- Timelines
- Challenges related to patient screening tools on the Web site

## Web-Based Recruitment

Based on the complexity of planning for Web development, our company and its clients have embarked on extensive country-by-country research into Web-based practices. This data is reported through interviews and actual regulatory or Web-based documentation.

The following are examples of the type of data collected to help support Web-based strategy and to document regulatory guidelines.

**Mexico.** Establishing a Web site for a clinical trial does not seem to be prohibited, but probably would be ineffective, says Gina Gorodezky, MD, Medical Director of IMIC, a Mexico-based CRO. "The Mexican population that participates in

## Multinational Web Plan

SPANISH		COMMENTS
Sites	11	<p><b>Guatemala.</b> Sites very interested in using the Web site to promote the trial according to CRA information. Availability of the Internet is greater than in Mexico. Web site content will be available in Spanish and should be submitted to Guatemalan EC.</p> <p><b>Spain.</b> The Royal Decree, most recently updated on March 3, 2008, neither specifically permits nor prohibits using a Web site for patient recruitment purposes. Spain has adopted the EU Clinical Trials Directive, which allows for patient recruitment methods. Spain EC (Centro Coordinador de Comités Éticos de Investigación Clínica) permits patient-targeted Web sites, which must be approved.</p> <p><b>Mexico.</b> GCP guidelines allow advertising for subjects, but have no mention of such methods as radio, TV or the Internet. Considering the use and availability of the Internet, this country is not recommended for use of the Web site.</p>
Cost	\$2,283	
Translation Due Date	TBD	
Live Date	TBD	
GERMAN		COMMENTS
Sites	29	<p><b>Germany.</b> No legal obstacle to patient recruitment through Web sites, which have been successfully used for many trials in Germany. ECs must approve the text and content.</p> <p><b>Austria.</b> Radio, newspaper, flyers, and Internet advertising are all possible. Ethics committee must review and approve all of the text. Web sites have previously been approved as a recruitment strategy for clinical trials.</p> <p><b>Switzerland.</b> The regulations make no mention of using Web sites to create awareness of a clinical trial or to screen potential subjects. It is worth noting that Switzerland is not a member of the European Union, so it does not operate under the EU Clinical Trials Directive. Considering stringent requirements detailing where the information is sent and the measures in place to prevent a Web site from targeting patients who may already be participating in another clinical trial, submission for Switzerland is not recommended.</p>
Cost	\$2,395	
Translation Due Date	TBD	
Live Date	TBD	
FRENCH		COMMENTS
Sites	21	<p><b>France.</b> ECs grant final approval of Web sites. The French Regulatory Agency (AFSSAPS) permits the use of Web sites for patient recruitment. Web sites cannot mention the product name, commercial name, logo or branding. Information permitted: the disease, the description of the clinical trial, the mechanism of action of the drug(s) tested, and the sponsor name. Those promoting the Web site in French-speaking countries will provide a URL that directs the user to the French version, rather than linking to the French version through the home page.</p> <p><b>Canada.</b> Many trials in Canada have successfully used Web sites to recruit subjects. English and French will be promoted.</p> <p><b>Belgium.</b> Belgium supports the EU Clinical Trials Directive and has one of the most efficient approval processes. The Internet is widely used, and sites are interested in using the Web to recruit patients. The concern in Belgium is the lack of a Flemish translation, which is why no submission of the Web site to the EC is recommended for this country.</p>
Cost	\$2,395	
Translation Due Date	TBD	
Live Date	TBD	

Source: D. Anderson & Company, 2008

Table 1. A Web-based recruitment plan for implementing a global Web strategy.

clinical trials does not have access to a computer,” Dr. Gorodezky says. She adds that screening of potential subjects is to be done in person.

Sergio Guerrero, MD, Vice President and Chief Operating officer of INC Research offers a slightly different opinion. He agrees that few prospective subjects would have access to a computer but comments, “This might change over time, once middle and high socioeconomic patient populations start participating in clinical trials. For now, it is limited.”

**India.** Estimates of Internet use in India vary from 21.1 million users—a mere 2% of the population—to 37 million, representing 3.7% of the population. Clearly, Internet use and availability is severely limited in India, although it is expected to grow.

While the regulations do not specifically mention the use of Web recruitment methods, the Indian Council of Medical Research (ICMR) posts on its site<sup>2</sup> a “Model form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC).”

In item 9, the PI is asked: “Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, Web sites—if so, kindly attach a copy).”

Regarding the likelihood of using recruitment Web sites, Pamrod Julka, MD, a professor of oncology at All India Institute of Medical Sciences in New Delhi, states, “The regulations do not disallow Web sites. However, this method may not be an effective patient recruitment tool simply due to the nonavailability of the Internet to a large proportion of people and illiteracy.”

**Austria.** ClinLife Austria is a registry of clinical trials (<http://www.clinlife.at/>) taking place in that country. Potential subjects can submit contact information after identifying studies of interest. That information is forwarded to appropriate investigative sites. It appears that the sites then contact the individuals and prescreen them over the telephone. An English transla-

tion of this service appears at <http://www.clinlife.co.uk/participating/how>, which is the UK version of this service.

In outlining the conditions for enrolling a compromised patient into a clinical trial, the Medical Devices Act mentions the posting of that trial on the hospital’s Web site. Therefore, posting of clinical trials on Web sites is clearly possible.

### **Global Case Study**

Table 1 on the previous page describes a multinational, Web-based recruitment plan. It includes actual research and translation costs for the countries mentioned.

This is meant to illustrate the level of detail, planning, and complexity involved in implementing a global Web strategy.

### **An Important Tool**

We have briefly illustrated the importance of Web sites as a recruitment tool and highlighted the level of complexity

## **Successful global recruitment campaigns are possible, but they require research, planning, and keen analysis of cost/benefit ratios.**

and the expertise required to implement Web recruitment on a global basis.

Successful global campaigns are possible, but success requires research, planning, and keen analysis of cost/benefit ratios.

Maintaining a realistic perspective and understanding the complexities of the process will help recruitment teams realize the many advantages of Internet-based patient recruitment initiatives.

### **References**

1. The PEW Internet Health Study, October 2006-2007.
2. [http://icmr.nic.in/human\\_ethics.htm](http://icmr.nic.in/human_ethics.htm).

**Melynda Geurts, MS**, is chief operating officer and a member of the board of directors, and **Lacey Blowers** is senior project lead at D. Anderson & Company in Dallas, Texas.