Branding Is Vital When Outsourcing Clinical Trials

Investigator Loyalty Depends on Recognition

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One of the objectives of late-phase clinical trials is to have as many physicians as possible exposed to the treatment under study. The end result, it is hoped, is that once physicians have gained experience with the treatment, they will continue to prescribe it after the trial has ended.

In fact, research has shown that physicians who act as investigators in clinical trials tend to develop a loyalty to the sponsoring company (see sidebar on page 32). But how does outsourcing a clinical trial to a Clinical Research Organization (CRO) impact the physician-pharma company relationship?

Until recently, pharmaceutical companies traditionally sponsored and ran clinical trials in-house. Today, outsourcing clinical research activities has become the norm. Sponsors turn to CROs for the efficiencies offered by their resource capabilities and expertise.

While outsourcing to a CRO has proven to be an effective means of running clinical trials, sponsors must keep in mind they are the main players in the game. As much as the CRO will become known to the investigators, the sponsor's name must be equally evident to the participating physicians.

Does branding work?

Branding is an effective way to ensure investigators know who is behind a study. When a sponsor works through a CRO, effective branding techniques might include:

- Training the CRO personnel working on the trial to be representative of the sponsor as much as to their own organization.
- Branding clinical trial materials to ensure the sponsor's name remains known to the physicians. If it is not possible or practical to brand all trial materials, at least certain key materials, such as the study's critical documents, should bear the sponsor's name and logo. Although certain documents, such as case report forms and informed consent forms, may not be branded, all site management correspondence to investigators should bear the sponsor's name, along with that of the CRO.
- Highlighting the sponsor's name and logo on all regular communications to the trial sites, such as newsletters and bulletins.

Working with a CRO must not jeopardize the development of close and loyal relationships between the sponsor and its investigators. To achieve this goal, the sponsor should consider assigning a project manager responsible for setting the direction and overseeing the CRO's activities.

The reporting mechanisms from the CRO to the sponsor should be defined at the onset. A successful collaboration is ensured by a close connection between the sponsor and the CRO, and the sponsor's trust that the CRO represents their best interest in the field. Together, the sponsor and CRO can build a relationship that will ultimately support the sponsor's product marketing efforts. CPM

To discuss how you can take every step possible to ensure your clinical trial leads to a more successful product launch, please contact Dr. Gabriela Radulescu, 1-800-811-9880, ext. 131 or gradulescu@phase4health.com.

Investigators loyal to trial sponsors

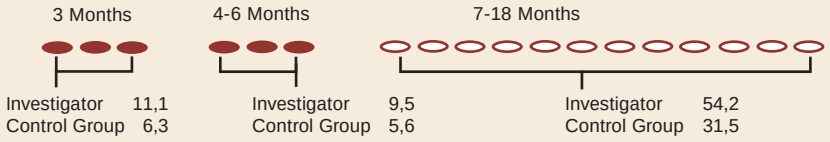
Research conducted by University of the Sciences in Philadelphia found that physicians who act as investigators in clinical trials develop a loyalty to the sponsoring company.

The study matched a randomly chosen sample of 2,108 clinical investigator physicians with a similar set of control physicians who had not participated in a clinical study within the past seven or eight years.

Investigator physicians wrote more prescriptions for the study drug than the control physicians at all three comparison points after the product's launch.

During the 18-month post-launch period, the clinical investigator group wrote an average of 75 prescriptions for the new drug, compared with an average 43 prescriptions each for the control physicians (Figure 1).

Figure 1. Post-Launch NRx: Overall



Source: Glass, Harold. Researchers and Marketers. Successful Clinical Trials Management, June 2004.