

Drug Development in a Multicultural Environment

Inna Kassatkina and Maria Canfield

Each stage of a drug's life cycle is touched by language, culture, and national infrastructure needs. Pharmaceutical and other life sciences companies selling their products internationally typically adapt the offer, the product itself, the language, the website, the marketing collateral, its way of selling, and who supports it to the needs of doctors and consumers in their target markets.

When it comes to international drug development, most people involved in the process immediately assume there will be language and regulatory concerns, thus adapting to the particular market. What about drug development in a multicultural environment without crossing international borders?

In the United States, compelling opportunities exist for drug developers and clinical researchers to boost value through strategic investments in cultural competency, health literacy, disease education initiatives, and grassroots partnerships. According to 2007 US Census numbers, among the 20 largest metro areas, more than half of all people over age five speak a language other than English at home. In Hialeah, Florida, and Laredo, Texas, more than nine-in-10 people age five and older speak a foreign language at home – the highest such proportion among US places of 100,000 population or more. The 10 places with the highest proportions include four cities in Texas and three in California.

In order for drug development companies to reach multicultural communities, it is important to understand the unique differences between specific cultures, and how to incorporate these differences into their primary communications with patients and research subjects. This article will identify the major considerations for communicating a message to a multicultural audience. It will address topics including cultural sensitivity, translation processes, and legal components related to translating materials into other languages.

Disease prevalence

The number of non-English speakers in the U.S. shows a clear need for linguistic and cultural adaptations in order to reach the growing Hispanic, Asian, and other ethnicities during the drug development process. Beyond sheer population numbers, there are also differences in disease incidence and severity between ethnic groups in the United States.

For the purposes of this article, consider the US Hispanic population, which, according to the Census Bureau's 2007 statistics, is 45.5 million and growing. This particular population is being highlighted in this section due to their significance demographically.

Following are a few examples of disease incidence, severity differences, and preventive treatment trends among the US Hispanic population.

- Hispanic men and women have a higher incidence of stomach and liver cancer than the white population.i
- Hispanic women were more than twice as likely as non-Hispanic white women to be diagnosed with cervical cancer.ii
- Hispanics are 38 percent less likely than non-Hispanics to have visited the doctor within the past year, according to the 2007 data from the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ).iii
- Hispanics have a rate of new AIDS cases over 3.5 times higher than that of non-Hispanic whites. iv

Genetic factors play a part in these differences, but lifestyle factors such as diet, smoking, screening for early detection, are essential, too.

Why? Hispanics tend to approach health care differently than non-Hispanic patients. That's according to a 2004 paper issued by Hispanic Research, Inc., which stated that, in general, Hispanics rely more on home remedies and over-the-counter medications, consult their friends and families more for medical advice, and tend to self-diagnose and self-treat. To reach Hispanics and other specific groups effectively, cultural differences must be understood. These differences relate to many aspects of everyday life: religion, family values, communication and social interaction, and diet.

There is significant opportunity for pharmaceutical companies to connect with various ethnic groups through print advertising, the establishment of medical contact centers to handle inbound calls, outbound compliance and persistency programs, self-serve interactive voice response (IVR) support, and community outreach. Currently, the response to non-English advertising by pharmaceutical companies falls short of desired levels; cultural differences must be understood to capture the intended audience. There are unique differences between specific cultures and how to incorporate these differences into primary communications and marketing materials.

Cultural practices and values can substantially affect a therapy's successful development and market adoption, influencing everything from disease diagnoses to a patient's definition of life. For example, in some Latin American cultures *simpatía* is an important word and cultural value. Translated as "congeniality" or "affection," the level of *simpatía* that patients perceive in the clinical setting influences how satisfied they feel with their care, potentially influencing their willingness to disclose their complete patient history, to adhere to treatment, to report adverse events, and to make follow-up visits.

Other drug development areas where project teams may need to recognize and adapt to cultural differences include values around the patenting of life forms, understanding patient-physician interaction, setting project milestones and endpoints, and recognizing decision-making authority in a community or organization.

Regulations and Guidelines Pertaining to Language Translation Issues

Regulations may prohibit or limit what you can say about a drug, its availability, or competitors. For good reason, the US Food and Drug Administration (FDA) has language requirements for documentation and filings. To research a drug successfully in the US, pharmaceutical companies may have to provide translation in dozens of languages.

In the United States, there are national standards on Culturally and Linguistically Appropriate Services (CLAS), developed by the Office of Minority Health, US Health and Human Services. These standards are primarily directed at healthcare organizations such as hospitals and clinics, but individual providers are also encouraged to use the standards to make their practices more culturally and linguistically accessible.

While not directed at pharmaceutical companies, the concept behind many of these standards has applicability to the thought process that goes into developing a marketing campaign that is either directed to a specific ethnic group or crosses ethnic lines.

The 14 standards are organized by theme. A summary follows:

Culturally Competent Care

- 1) Ensure care compatible with cultural health beliefs and preferred language
- 2) Provide diverse staff reflective of demographic characteristics of service area
- 3) Train staff in culturally and linguistically appropriate service delivery

Language Access Services

- 4) Provide language assistance services at no cost

- 5) Provide patients services in their preferred language
- 6) Assure competence of language assistance provided
- 7) Provide and make available easily understood patient-related materials

Organizational Supports for Cultural Competence

- 8) Develop written strategic plan relative to providing CLAS
- 9) Conduct initial and ongoing organizational CLAS self-assessments
- 10) Collect data on patient's race, ethnicity, and spoken/written language in health records
- 11) Maintain demographic, cultural and epidemiological (study of factors affecting health and illness) profile of community and plan to respond to cultural and linguistic characteristics
- 12) Develop participatory, collaborative partnerships with communities
- 13) Ensure conflict and grievance resolution processes are culturally and linguistically sensitive
- 14) Encouraged to make available their progress in implementing CLAS standards

Additionally, there is mandated protection for patients with Limited English Proficiency (LEP)^{vi}. Regarding clinical research, translation guidelines have been set by the Office for Human Research Protections (OHRP) and the FDA. There are FDA regulations that also govern language translation for medical device and pharmaceutical product marketing.

Incorporating Language and Culture into Your Drug Development Strategy

Drug development strategies should include expense and time estimates for translating documentation to and from local languages, especially for clinical trial forms and documents, and should factor in costs and time for developing language strategies.

The demographics and (by extension) culture of the users and potential users of a marketed drug should be factored into both advertising campaigns and educational/support/access initiatives (IVR, inbound medical affairs programs, outbound compliance, and persistency programs).

Communication problems, proper drug usage, and issues of true and informed consent can occur when treating non-English speakers. The *Journal of the American Medical Association* demonstrated in studies in 1995 and 1999 that the number of Spanish speakers who had difficulty understanding written instructions in English was almost double that of the English speakers presented with the same instructions.

In addition to language barriers, consider cultural values.

Different cultures (as well as age group subsets and genders) may demonstrate preferences for particular communication channels (telephone, email, Internet, face-to-face) based on individual taste and language skill, ease of availability and use, cultural influences, and confidentiality considerations. According to a 2008 report by the Pew Hispanic Center, about seven in ten Latinos reported that they received information from a doctor in the past year, with an equal proportion obtaining health information through their social networks, including family, friends, and church/community groups. An even larger number (83%) reported that they obtained health information from some branch of the media, with television being the dominant source.^{vii}

The survey findings clearly demonstrate the power and potential of these outlets to disseminate health information to the Hispanic population. For example, the leading form of media that Hispanic adults say influences their decisions is television.^{viii} Therefore, consider the preferences, as well as the variety of alternate communication methods, when reaching out to different demographics.

Managing the Translation Process

To comply with the laws and ensure that people get the right treatment, organizations must keep the information they publish up to date and consistent across all of their packaging, websites, and marketing

materials. Consistency across documents and channels is hard enough in just one language, but it gets more complicated as you add the process of translating into other languages.

To reach non-English speakers, pharmaceutical companies typically outsource to language specialists in the medical translation industry. Depending on the volume of languages and documents to translate, this can sometimes result in working with multiple vendors. To ease the process, centralize the translation process. Therefore, it is important to manage content across multiple locations and translation providers via centralized content management systems and translation memory (TM) tools. Further, by centralizing translation management via one department, a core contact team, or even a designated project manager, organizations can streamline their translation procurement efforts in a more effective, and, often less expensive, manner. This will help organizations manage multiple languages and numerous translation vendors or vendor locations, resulting in faster turnaround times and fewer translation errors.

Concluding Thoughts

In today's multicultural drug environment, drug development strategies must include expense and time estimates for translating documentation to and from one or more languages. Incorporating language and culture into the drug development process plays an important role in meeting product demands. If not, mistakes from poorly done translations can result in product delays, increase in costs, or, even worse, contribute to product liability lawsuits.

Develop a communication plan and strategy that outlines what methods will be used to address the language and cultural factors most important to the project outcome, as well as for anticipating how confidentiality, LEP, and other legal regulations affect your organization's decision to translate documents (and which ones to translate).

And finally, remember that not everyone speaks English. Since 1990, the number of non-English speakers at least doubled in six U.S. states.^{ix}

Inna Kassatkina is co-founder and president of Global Language Solutions (www.globallanguages.com).

Maria Canfield is Vice President, Client Services for Alliance Healthcare Information, LLC

i Cancer Facts & Figures for Hispanics 2006-2008

ii National Cancer Institute. Surveillance, Epidemiology, and End Results. Bethesda, Maryland: National Cancer Institute, 2002.

iii Agency for Healthcare Research and Quality (AHRQ), "2007 National Healthcare Disparities Report."

iv Agency for Healthcare Research and Quality (AHRQ), "2007 National Healthcare Disparities Report."

v Felipe Korzenny and Betty Ann Korzenny, "Hispanic Marketing: A Cultural Perspective" (Burlington, MA: Elsevier, 2005).

vi www.lep.gov

vii "Hispanics and Health Care in the U.S.: Access, Information, and Knowledge," a joint report by Pew Hispanic Center and Robert Wood Johnson Foundation Research. (2008)

viii HispanTelligence and TNS Media Intelligence as cited in Ad Age "Hispanic Fact Pack: Annual Guide to Hispanic Media and Marketing 2008 Edition," July 2008.

ix 2000 U.S. Census