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Human Factors in Pharmaceutical Labeling

How human factors can make development and evaluation of drug safety communications faster and more effective

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Under FDA regulations, drug labeling plays a starring role in the communication process, with medication guides, product websites, safety communications, and even advertisements as the supporting cast. Development and evaluation of communications in this context can be complicated by the number of stakeholders, including healthcare professionals and patients, the amount and complexity of information, and FDA regulatory requirements and expectations. Although pharmaceutical companies have historically relied on FDA-mandated surveys to evaluate their communications, traditional surveys and standard methods may not provide the detailed product-specific insights required to meet increasingly stringent requirements. To address this new challenge, pharmaceutical companies can benefit from a multidisciplinary approach to developing and evaluating their suite of communication materials.

Here at Exponent, pharmacoepidemiology and human factors experts work together to assist pharmaceutical companies in their development and evaluation of drug safety communications. Our cross-disciplinary approach was developed to provide pharmaceutical companies with powerful and focused methodologies, robust data, high-quality analyses, and actionable information. Scientific human factors methods can be used to assess prescription and over-the-counter drug labeling, risk mitigation and evaluation strategies (REMS), and other safety communications. These methods can also be leveraged to uncover potential improvements to websites, training programs, packaging, and more.

Challenges in Drug Safety Communication

A significant challenge in drug safety communication is that complex information must be communicated to both healthcare professionals and nonprofessionals through words, tables, figures, and diagrams. To gain FDA approval for over-the-counter medications, companies must be able to demonstrate that consumers can read a label, understand it, and make an appropriate decision about whether and how to take the drug. In recent years, there has been an increased FDA focus on communications, especially when prescription medication use errors occur. Even ancillary communications, such as advertising and informational websites, can be subject to increased regulatory scrutiny and usability expectations.

FDA has also been turning a more critical eye to methods for evaluating communications. Companies have been required by the Administration to address significant amounts of critical feedback. FDA has also provided detailed guidance about the need to consider and evaluate patient and consumer knowledge, attitudes, and behaviors. If existing communications fail to meet stringent assessment criteria, FDA could require additional risk mitigation strategies.

Drug communications are intended to support effectiveness and safe use conditions by addressing, for example, the potential for under- or over-dosing, discontinuation, or the occurrence of potentially avoidable events such as drug-drug interactions. While addressing FDA critiques can be challenging, the goal is to help ensure that communications are understandable to the end user and support safe use conditions. The position of the FDA is that communication issues may ultimately impact a medication's perceived benefit-to-risk balance, which is the basis for market authorization.

Improving Evaluations with Human Factors

Surveying patients, pharmacists, or providers can offer some insights on whether they've sought, read, interpreted, and applied information correctly.

However, surveys often face issues with execution, such as low response rates, imprecise questions, and ill-defined or inefficient sampling plans. Working with a human factors team can help companies design and implement surveys using patient- and provider-friendly language, construct targeted questions to explore different concepts, and parse out nuances in participant knowledge, attitudes, and behaviors. Targeting assessments and measurements to minimize sources of variability can also help reduce the minimum sample size needed and result in faster turnaround times. In the event that regulators ask for more information or alternative methods, human factors experts can help companies formulate a response that considers the scientific, logistic, and regulatory issues.

Going Beyond Surveys

Surveys are not the only method to evaluate drug communications, and they may not always be the best method for a given situation. Alternative methods, such as interviews and focus groups, can be used, but finding the most appropriate respondents and knowing how to work with the data can be complicated for those who aren't well versed in behavioral science. These problems can be compounded when the drug at issue is intended for use in pediatric, elderly, or disabled populations. We apply our background and knowledge to develop rigorous and tailored evaluations of communications, to provide information needed to make data-driven, scientifically-informed decisions. Indeed, our clients find that engaging pharmacoepidemiology and human factors experts in their communication evaluations from the outset can help to anticipate and address FDA's concerns without adding resources to manage the process as it progresses.

The bottom line? By working with a multidisciplinary team that includes pharmacoepidemiology and human factors expertise, pharmaceutical companies can position themselves to rapidly identify and address issues with communications and maintain regulatory compliance.

How Exponent Can Help

Exponent's pharmacoepidemiologists and human factors scientists leverage deep subject matter expertise and cutting-edge techniques to evaluate and improve how risks and appropriate use conditions are evaluated and communicated. The team focuses on a variety of fields and specialties including psychology, sociology, behavioral science, cognitive ergonomics, risk communication and perception, and more. Our human factors and pharmacoepidemiology experts have a variety of methods and tools at their disposal for survey design, interviews, focus groups, root cause analysis, and user testing.

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