The Trial NEVER Ends

After years as a staple of late-stage clinical trials, patient reported outcome surveys are expanding their role in drug discovery and development processes.

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For pharmaceutical companies, information is power. To gain that power, many drug companies use patient-reported outcomes (PROs) to measure the impact and effectiveness of their drugs during Phase 2 and Phase 3 clinical trials. The success they've experienced using PROs has prompted expansion of the way these tools are utilized. Drug developers have found that the information gathered can be used throughout the entire clinical trial continuum—and beyond.

Discovering New Opportunities

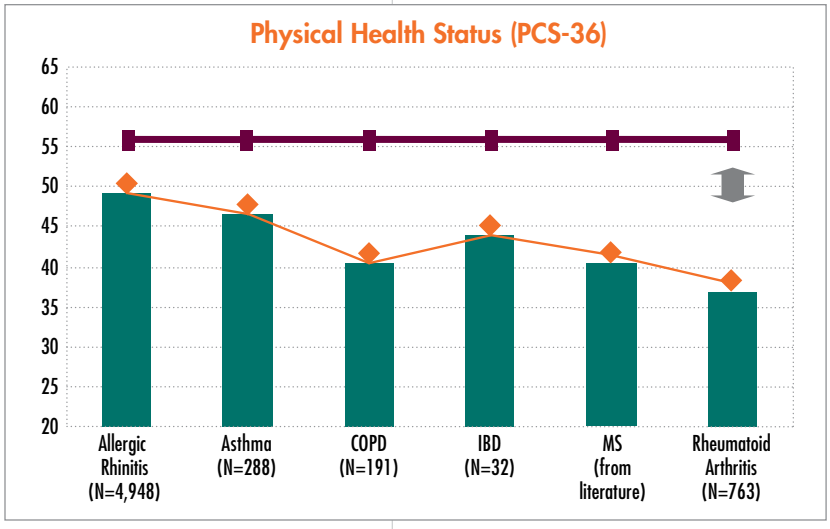
Where should a drug company invest its time and money? To answer that question, a growing number of companies are using PROs at the very outset of the drug development process.

Early observational and epidemiology studies can identify unmet clinical needs and potential profitable drug markets. For example, PRO health surveys can be used to quantify the physical-health burden of certain diseases (See Chart 1). The results can then be used to compare adults with those diseases who are receiving standard treatment against average healthy adults. The differences in their survey scores point to unmet needs for individuals with the diseases in question. The same can be done to assess the impact of diseases on mental health.

Once the areas of greatest need are identified, a drug company can make informed decisions about whether it wants to try to develop products to fill those needs. If the company decides to move ahead with a drug, it will begin with valuable insights about the target audience.

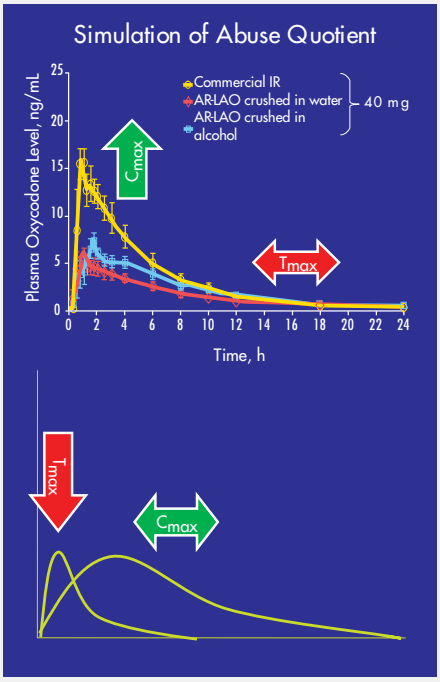
Making the Case

Jump forward now to the drug's release date. The drug developer has met many challenges, but just as many lay ahead. While the drug



Height of bar indicates the average score for the average patient with average comorbidities receiving average treatment. The red line represents respondents with none of these conditions. (Source: QualityMetric)

The Question of Opioid Euphoria



As prescription analgesics continue their ignominious climb up the list of the most frequently abused drugs in the United States, pharmaceutical companies are under increasing pressure from federal legislators and regulators to do more to prevent the misuse of their products. Unfortunately, while there are several theories as to what properties of prescription opioids contribute most to their abuse potential, there has been almost no research conducted on the subject.

In an article available only on the *Drug Discovery & Development* Web site, Dr. Lynn Webster, a specialist in both preventative medicine and addiction medicine, discusses a recent study she conducted to determine how two pharmokinetic factors, maximum plasma concentration (C_{max}) and time to maximum plasma concentration (T_{max}), relate to the abuse liability of oral oxycodone. In order to describe their relation, Dr. Webster has coined the term "abuse quotient", or AQ. As the name implies, researchers divided the C_{max} by the T_{max} to arrive at the abuse quotient, a measure of the potential for misuse. The higher the AQ the more likely a given form of oral oxycodone is to be abused.

To gain insight into this complicated issue, Dr. Webster provided various commonly prescribed formulations and dosages of oxycodone to dozens of test subjects. Shortly thereafter, she administered a drug effects questionnaire to better understand how the participants were affected.

To read the full article and see the results of this randomized, double-blind, multi-cohort study, go to *www.dddmag.com* and click "The Question of Opioid Euphoria" in the Recommended Reading section.

may have been proven to be safe and effective, the company still must get the drug to the people who need it. PROs can also be used to achieve this.

PRO data can help convince pharmacy benefit managers and insurers to include a drug in their formularies. Companies are successfully using PROs to prove the positive impact of a product on patient health and, ultimately, health expenses. Health surveys are also being used to answer questions about comparative effectiveness in order to build an economic basis for formulary inclusion. The bottom line is PROs can help make the case that a drug will lower claims costs over time. The same information can be used to educate doctors and other healthcare professionals. When they see proven results, they are more likely to recommend and use a drug to treat patients.

Expanding Markets

PRO health surveys generate information that is tailor-made for marketing a product. Consumers want to know what a drug does and how well it works. PRO results can be used to educate them about a drug's value, and encourage patients to ask their doctor about it. Marketing professionals can use PRO data to create well-defined marketing communications such as ads, brochures, educational materials, and Web sites that increase brand awareness and promote sales.

Companies are also using online PRO health surveys to generate Web traffic while engaging and educating consumers. In 2006, **Bristol-Meyers Squibb** introduced *RAliving.com*, an online source of information for patients suffering from rheumatoid arthritis. On the site, patients are invited to take a short health survey. Participants receive a report of their results, which includes an age- and gender-adjusted comparison of their physical, emotional, and overall health to that of the U.S. general population. They are also encouraged to share the results with their physicians, and to return to take the survey again in the future to monitor their progress.

Applications such as these provide drug manufacturers with the opportunity to create a unique, ongoing dialogue with a large number of consumers. By educating consumers about diseases and possible treatments in this way, companies can help ensure that people who need their products know about them and talk about them with their doctors. At the same time, online surveys can gather valuable information to help companies better market their products and meet consumer needs, while improving their understanding of the longitudinal impact of their products on functional health.

Meeting Responsibilities, Reaping the Benefits

Through post-marketing surveillance, a drug company protects the safety of consumers—and its reputation. However, once a new drug

is made available, and the controlled environment of the clinical trial is gone, it can be difficult to monitor drug response and effects. Web-based and interactive voice response (IVR)-compatible PROs can simplify the process. These technologies can make it easier to monitor consumers on a large scale, while helping to ensure data accuracy. Additionally, the ability to measure and track the health status of individuals and large groups over time is very important to health-registry developers.

One attractive benefit of tracking a drug in this way is that it may reveal new applications for the drug. The results also can be used to substantiate label claims. The recent MAPI PROLabels Adhoc Research Report[1] found that at least 35 drugs or biologics currently on the market include label claims based on PRO surveys. These drugs include Humira, Arava, Thyrogen, Clarinex, Allegra, and Lyrica. In the Arava case, PRO data was not only used to gain approval from the **US Food and Drug Administration** (FDA) for a label claim, it actually sped up the process.

Body of Evidence

By using PRO surveys at every stage of the drug development and distribution process, a drug company can accumulate an impressive body of data that can enable it to meet the demands of all interested parties, from the FDA and health insurers to doctors and patients. The company can also solidify its position as an industry leader by consistently finding and cultivating profitable new markets. Through innovative uses of PRO health surveys, drug developers can meet the ever-growing challenges created by increased competition and regulatory requirements in a world where the trial never ends.

References

1. PROLabels Adhoc Search Report, Overview of Patient-Reported Outcome (PRO) claims or submissions using QualityMetric tools, Report QM-1097, Prepared by the MAPI Research Trust. May 6, 2008.

Gus Gardner has more than 21 years of senior management experience across several sectors of healthcare. At QualityMetric, he is responsible for the day-to-day operations of the company. Previously, he was first senior vice president/COO and then president, US, In-vitro Diagnostics Division at Clinical Data, Inc. Gus began his management career as an officer in the U.S. Marine Corps.