Ask your doctor

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When seeking a licensing partner for a product in development, market projections and strategies require substantiation. This can be provided through physician interviews.

Do you know the market for your products? You may think you do, but a surprisingly large number of companies end up having erroneous ideas about their customers' needs. Flawed market projections can jeopardize your ability to find a licensing partner or, worse still, lead to failure of a product launch. Although you may understand what experts in the field believe, prescribing physicians often look for very different things in a new product than do so-called key opinion leaders. Thus, on the basis of expert advice, you may believe you understand your market when, in fact, you understand only a small segment. This is why physician interviews can prove extremely useful in building your business.

We have personally conducted more than 700 60-minute interviews with physicians about products in development. We use these interviews to assist in valuations and preparing partnership discussion materials. For drug developers, there are two general reasons to conduct physician interviews: to find ways to improve your product and to convince a partner to work with you on terms favorable to your company. In the remainder of this article, we discuss how to manage physician interviews to help achieve these goals.

The target product profile

Before talking to physicians, you need something to discuss. Physicians must have enough information to evaluate your product and provide meaningful feedback (**Box 1**). A one- to five-page document, called a target product profile (TPP), may be used to describe the product to physicians. This

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Box 1 Creating a meaningful target product profile

Creating a target product profile is a pivotal part of the process of obtaining feedback from physicians. Here are five rules you should follow when preparing such a document:

- Describe the finished product in US Food and Drug Administration label language
- Avoid advocacy—don't go beyond the label claims in the target product profile
- Focus on (projected) clinical results
- Assume nothing about dosing and administration
- Discuss the concerns you have about the product

is where a science-driven company may err, as doctors are more familiar with evaluating products based on US Food and Drug Administration (FDA) labels instead of on scientific papers. Rather than writing a technical paper, you should present the highlights from what you believe your FDA label will eventually look like. You should familiarize yourself with FDA label language from products similar to yours, which can be found on the FDA's website.

Make sure you do not go beyond the anticipated FDA label in the TPP. Sales representatives will be able to address these 'label claims' but will be restrained from discussing most data outside the label. What does this mean for you? If your regulatory expert believes the indication will be mild-to-moderate asthma, don't say "and may be appropriate for other respiratory conditions, including severe cases" in the TPP. Advocacy is important, but a physician interview is a place for analysis alone.

It is good practice to project the number of patients that will be tested in phase 3 even if you are in an earlier stage of development. If you present the patient numbers you have from earlier stages, or if you have no clinical data at all, then physicians will be biased against the data you do present. Because you are attempting to gauge physician adoption of your product once *all* clinical trials are com-

plete, present *projected* phase 3 trial patient numbers in the TPP. If otherwise unknown, phase 3 trial sizes may be estimated roughly from other FDA labels for products approved for the same indication. Presenting preclinical data (even if otherwise compelling) may simply convince physicians that the product is in early stages and cannot yet be evaluated. "I've never once treated a rat," one interviewed physician said to us when presented with otherwise strong preclinical data for a melanoma product.

One area in which companies often trip up is in providing a minimal description of dosing and administration. These things matter, and they especially matter to physicians. What's more, these areas are the ones in which most scientifically minded companies (and key opinion leaders) have the least common ground with their customers. In our experience, some of the most consequential but solvable problems are in dosing and administration (**Box 2**). These problems may make or break a product launch if not discovered and resolved.

Finally, if you have a concern that could damage your product, discuss it with physicians. Include a projected adverse event table along with projected warnings and contraindications. You may be surprised to find that what you think matters actually does not bother physicians. If the factor is a concern to

Box 2 Just what the doctor ordered

Physicians can provide feedback that is useful for many aspects of product development. Here is a real-world example: an intravenous drug has to be infused in the office and an alternative dosage form would be oral and taken at home. Which would physicians prefer? We have worked on projects in which physicians declared each dosage form the clear winner. For a chronic fatigue syndrome treatment, physicians believed getting the patient to come into the office often would be difficult and would monopolize office space, so the oral drug was much preferred. For an oncology product we reviewed, however, physicians were reimbursed more favorably for infused products than for oral products and also could ensure compliance by using the infused product, so that form was strongly preferred. We have observed enough counterintuitive reactions to product strength, dosing regimen, packaging and methods of administration to recommend that companies pay close attention to dosing and administration in the target product profile.

physicians, you may ask about ways to mitigate the downside. This will allow you, when you do approach partners with your primary interview results, to say confidently that you have spoken with physicians and they do not believe issue X will be a problem, or that they suggested solutions Y and Z.

Conducting the interview

A friendly physician interview is unlikely to be useful. Instead, you are better off interviewing physicians at arm's length—ideally through a skilled third party and certainly with physicians who do not have an existing relationship with you or your company.

Once you have lined up your physicians (you will typically pay an honorarium), there are two general steps to take to conduct a productive interview: make sure you understand both the physician's current practice and his or her response to the TPP. About half of a 60-minute interview is typically spent understanding the usage patterns and patient population surrounding different pharmaceuticals. Patients may exist in practical 'buckets'—meaning different subsets of patients receive different types of treatment. Examples of bucketing include differences based on age, disease severity or co-morbidities. Before a physician interview, you might have an idea of how patients are segmented by practicing physicians, and scientific papers and treatment guidelines are sometimes helpful. Still, the only way to get real-world information is to ask.

Once you understand the patient buckets and how each is treated differently, you are in a position to discuss how your product fits in. Present the TPP and then ask about advantages, disadvantages and anticipated use in each patient bucket until you thoroughly understand how often, for whom and why this physician might use your product. If there are additional pieces of information (especially anything that would be in a pub-

lication but not on the FDA label), you may present that to test if the physician is 'promotionally sensitive' to particular messages (a company's medical science liaison is able to discuss scientific literature outside of the FDA label, so it's meaningful to explore what scientific information would be compelling to physicians).

Finally, we have not found it useful to discuss price with physicians in most cases. Physicians are quick to say that price is a major factor for every product. However, these same physicians are often unable to say what similar, existing products cost. Instead of asking about price, ask physicians how they will react to secondary effects of price. That is, physicians work in a world in which third parties seek to restrict what doctors prescribe. These restrictions may include formulary placement, step edits (required use of drug A before drug B may be prescribed), prior-authorization requirements, unfavorable product reimbursement or medical exemption requirements. Ask physicians what restrictions (from such payers as the government, insurance companies or hospital administration) they believe will be placed on your product and how their use of it might change if additional restrictions are added. Payer interviews will then inform you of what restrictions may be in place at different price points, so you may estimate changes in use from changes in price.

Improving the product

The results of primary physician research can often provide crucial insights into actions you may take to improve perceptions of, and ultimately use of, your product. In short, you can learn the product features that matter most to physicians and then figure out how to craft convincing marketing messages.

Clinical results are often the primary drivers for market uptake of a product, so it makes sense to listen to what physicians have

to say about your planned clinical trials. Are the proposed endpoints the right ones? Is the comparator arm relevant to the physicians? Will patient numbers be large enough to convince a community physician? For a diagnostic, do physicians care most about sensitivity, specificity, positive predictive value or negative predictive value? (Different trial designs will tend to maximize different values.)

One example we found was a walking test. For neurologists treating patients who had multiple sclerosis, walking was an ideal endpoint that meaningfully described a patient's ability to function. In another setting (chronic fatigue), physicians believed the amount of time walking on a treadmill had little clinical relevance. Physicians viewed what appears to be the same endpoint (walking) very differently in different contexts.

In another example, the time the physician had to spend monitoring the patient for adverse events after administering a cardiac diagnostic was viewed as a 'straight-to-the-pocketbook' endpoint (lost physician time), and we were able to advise our client to include patient monitoring time in the planned phase 3 trial. In our experience, understanding what clinical data would support effective marketing messages is well worth the effort before phase 3 begins.

Another area that is often overlooked—and can leave substantial gaps in product valuation efforts if ignored—is a thorough understanding of health economics (how the use of a treatment ultimately may save money for the payer) for a new drug. Studies that provide supportive rationale for reimbursement decisions are not always at the front of physicians' minds. However, knowing how doctors are incentivized to use your product should be an area of focus during primary research. Our example of oral versus infusion dosing (Box 2) highlights how a lack of objective, realistic discussions with treating physicians can prevent a product from being developed in a formulation doctors will be inclined to use.

In many therapeutic areas, especially those affecting elderly populations, physicians carefully weigh the impact of adding another drug to a patient's regimen versus the impact on quality of life. Too often, those details are not even considered in clinical studies or are uncovered only during partnering due diligence (or even worse, in a post-launch analysis of a product's poor performance).

Gaining a thorough understanding of the logistics of how healthcare providers actually use your product can also help maximize value and minimize barriers to adoption. Often, physicians and nurses have preferred

packaging and dosage forms, and preference may well trump efficacy and safety for many products. In one instance, physician interviews showed us that the time necessary to warm our client's product to room temperature was a concern given the circumstances in which it would most likely be used. In another, our client proposed supplying its product in vials that did not contain enough active pharmaceutical ingredient to dose the typical range of patients, which meant multiple vials, wasted product and wasted time. Dosage and packaging have dramatic impacts on market share because these things matter to physicians.

Use in partnering

In our experience in partnering discussions, we've noticed that whichever party has talked to the larger number of physicians has more credibility. Quotes and other qualitative observations trump unsubstantiated beliefs held by companies and their potential partners (as they should). To get a large physician sampling, use quantitative Internet surveys following qualitative interviews.

Because credibility is the keystone of partnering discussions, partners must believe that you understand the market in detail and that any pitfalls have been uncovered. Your part-

ner must see that the TPP used in your physician interviews was not an advocacy piece but an unbiased analysis piece. Partners will be generating and comparing revenue estimates based on their own physician interviews. If you have presented your product in detail to physicians, your market share estimates will increase in credibility.

There is an important translation between what physicians say they will do in terms of market share and what they actually do. Physicians (and consumers more generally) are thought to overestimate when asked to predict future use of a new product. Some companies automatically apply a 33%–67% reduction on market share results or adjust usage share by zeroing out responses that came from physicians who did not make the top one or two boxes on an intent-to-prescribe scale (answered 6 or 7 on a 1–7 scale). There is no universally adopted rule for translating physician intent into physician action, but credibility in the process helps in defending a high projected market share during negotiation.

There are three reasons why partners discount market share projections: the TPP was an advocacy piece, potential pitfalls were not discussed with physicians or physicians were 'detailed' (sold) on the product. You need to come down on the right side of all three aspects. It has been our experience that if you are rigorous about bucketing patients, discussing pitfalls in detail and presenting your product in an unbiased manner, partners are much more willing to accept your market projections.

Conclusions

Talking to your customers via physician interviews is the strait and narrow gate to product improvement and successful partnering. A meaningful interview process may lead to course corrections before it's too late and can help position a company for success in the market. A credible physician interview process will allow your partners to accept the market values you project and will help you reach a partnership based on mutual trust.

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