INDUSTRY FORUM

Primary Marketing Research for Forecasting

Context Is Everything

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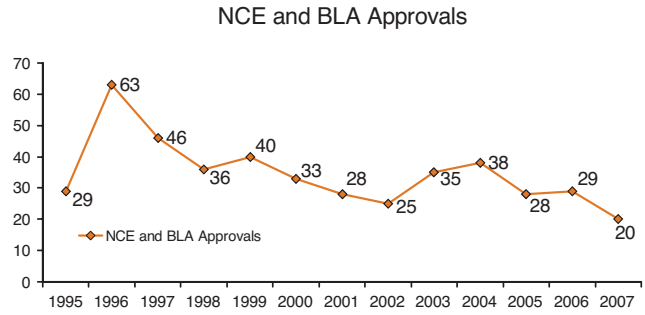
Unless you have been completely buried in research projects, you are acutely aware that the pharmaceutical industry has had a rough time of it during the past decade. Specifically, the collective industry pipeline is thinning, sending companies scrambling in all directions for solutions. Analysis of product approvals over the past 12 years shows that the peak in FDA authorizations experienced in the mid 1990s has reversed itself in subsequent years to the 2007 result of only 20 approvals, the lowest during that entire time frame.

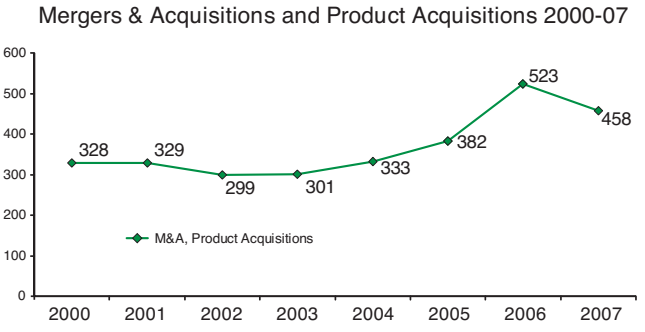
figure 1



Source: FDA, Pink Sheet, MattsonJack Internal Database

This dearth of new products has at least partially translated into growth in a related trend, the number of mergers and acquisitions in the pharmaceutical industry. As Figure 2 indicates, the number of mergers and acquisitions has grown every year from 2002 to 2006 and peaked at 523 in 2006.

figure 2



Source: Recombinant Capital

As a result of these trends, accurate, comprehensive product forecasting has taken on mythic importance in the pharmaceutical industry. More than ever, there is the need to precisely map out steady revenue streams from just a few developmental product possibilities or in-licensing candidates. The pressure is especially intense in the new product area as there are more unknowns for a variety of factors than the known patterns that emerge for an inline product.

The Challenge for Primary Marketing Research

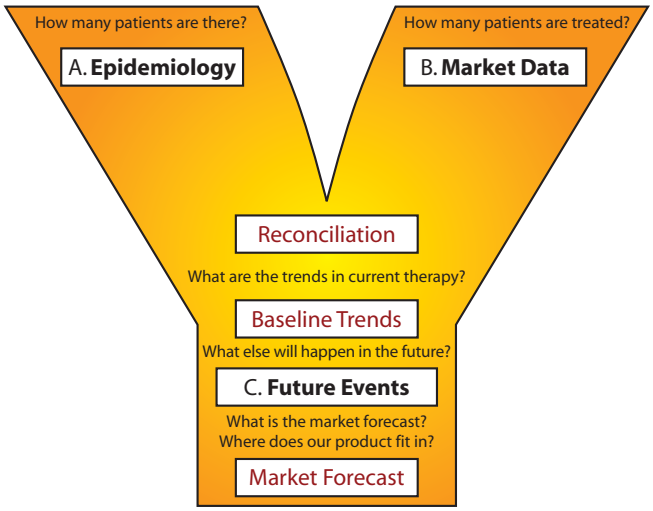
As a major input into the new product forecasting process, primary marketing research has been required to match this need for increasing accuracy and complexity, step for step. This need has necessitated the development of a more thorough research project planning process. It has also mandated the widespread understanding of the pros and cons of each of the potential research methodologies to be applied in these ever-more-critical product forecasts. This means that clarifying and communicating all possible perspectives surrounding a product forecast and related primary marketing research program is vital to overall outcomes and predictive success. The following highlights and hopefully simplifies the most common steps in the process of integrating primary marketing research into the forecast.

Forecasting 101

To start, it is helpful to review the overall approach to new product forecasting in order to more clearly understand the role of primary marketing research within the process. While there are several alternative methods to developing a new product forecast, generally speaking the route progresses

from sourcing epidemiology and market data, then to reconciling the differences in these sources, to trending off the unified data to start a forecast and then adjusting the data/forecast for future events. This path is illustrated below.

figure 3



Now let's discuss how primary marketing research can play a role at the three most appropriate and important steps in this process.

A. Epidemiology

An investigation of epidemiology is generally the starting point to most patient-based forecast models. Assessing the number of new (incidence) and existing (prevalence) cases of a particular condition during a given time interval is the starting point for analyzing the eventual opportunity for a new therapy to treat a certain number of those patients. It is important to note that primary marketing research is not typically an ideal source of epidemiological information. There are many reasons for this, but the biggest drawback is the accuracy in having patients or caregivers accurately assess the state of a diagnosis in an interview on a scale large enough to have some robustness for analytical purposes.

> … the starting point for analyzing the eventual opportunity for a new therapy …

Nevertheless, there are situations when primary research can be used to fill in gaps in epidemiological data for input into a forecast. Specifically, there may be certain patient populations where no prior data has been collected or there may be certain countries or regions lacking in epidemiological data. In these cases, a well-designed primary marketing research study has served admirably in accurately providing an assumption in a product forecast.

B. Market Data

While analyzing epidemiological input into their forecast, forecasters are simultaneously assessing what is known as "market data" assumptions in their model. In this step, the opportunity to apply primary marketing research techniques increases, sometimes significantly. This is because of the greater potential for gaps in this type of information from existing sources, depending upon the specific product situation. To start, market data broadly includes information for the forecast related to:

- Number and types of patients treated
- New patient starts/switches
- Lines of therapy/concomitant use
- Market share (patient/Rx/revenue)
- Length of therapy
- Compliance
- Impact of formulary/insurance
- Share of voice (SOV)
- Promotional response modeling (PRM)
- Direct-to-consumer (DTC) advertising
- Linkage of diagnosis to prescribing

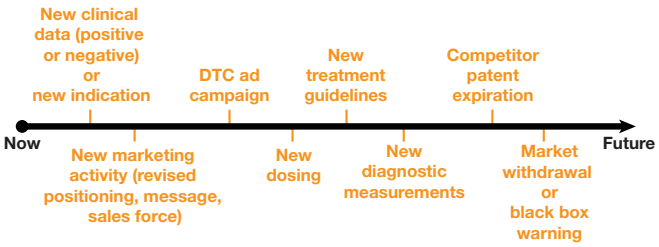
For each piece of market data that is missing from some other secondary source, primary marketing research can be used to fill in the gap on one of the topics listed above, sometimes very effectively.

C. Future Events

After epidemiological data and market data have been reconciled and then trended out into the future, the forecast is then adjusted for future events. Future events represent the greatest potential for applying primary marketing research to assumptions in a new product forecast.

Future events can include the following types of situations:

figure 4



Since each of these situations is new, there is less chance that existing epidemiological or market data is available or applicable to the assumptions in the forecast. As a result, primary marketing research is the best means of capturing data on these topics to apply to the forecast. This is why primary research is done in various forms to assess a new product. Typically, there is some aspect of the new product, improved efficacy or tolerability, which requires testing in terms of physician or patient receptivity to the new feature. The findings from this type of study are then applied in terms of an adjustment to the existing assumptions regarding product uptake in the forecast. Sometimes there is a tendency to focus on future events that pertain specifically to the company's own product. Equally important is assessing and predicting actions or situations that competitors may impart on the success of your product. Therefore, a process for identifying and assessing future events is critical for marketing research input into the forecast.

Key Drivers Regarding Primary Marketing Research Input Into Forecasting

Up to now, we have been assuming that the situation for every product is the same in terms of trying to populate the epidemiology, market data, and new event assumptions within the forecast. The reality is that the level of primary marketing research as input into forecasting is contingent upon two factors:

1. Product Situation—Urgency/Timing to Complete Forecast

- The specific product situation measured by "time to assess" significantly impacts:
  - Type and scope of forecast developed
  - Corresponding type and scope of information gathered to populate forecast

2. Availability of Relevant Data

- The availability of existing information (secondary data) to populate forecast assumptions is which in turn is affected by:
  - Specific scenario in terms of treatment area for the forecast
  - Past experience/analogue availability

Starting with the first factor, the more urgent the product/forecast situation, the less time there is to conduct any type of primary marketing research to support forecast assumptions at any of the steps in the process. Unfortunately, this situation happens quite often in new product assessments such as acquisitions or in-licensing evaluations. In contrast, the lower the urgency for completion of a forecast, the greater potential there is to conduct primary marketing research to more adequately support forecast assumptions. This happens more often for internally developed new products that progress through stages of clinical approval.

The second factor influencing primary marketing research is the availability of relevant data for the forecast. If a plethora of appropriate and applicable data already exists for the forecast assumptions, there will be little need for primary marketing research. The less data that already exists, the more likely primary marketing research will be needed to fill the gaps in information.

The graph in Figure 5 summarizes the intersection of these two factors and their impact on primary marketing research input into the new product forecast. Primary marketing research is the most abundant when there are significant gaps in market data and there is less urgency for completing the forecast (lower right in the graph).

This graph represents a continuum of primary marketing research input possibilities. To simplify this continuum somewhat, we have developed nine possible intersections (Figure 4) of product situations with data availability. The three product situations include:

1. Acquire/or In-licensing a Product – can be Phases I, II, or III, where timing to assess is short (typically four to eight weeks) and timing to launch depends on the product—so it could be short or it could be long
2. New Development for In-line Product – typically Phase IV, such as a new indication or a new competitive set where timing to assess varies
3. Company-owned Product in Development – usually Phase II products where timing to assess is longer and the product is still years away from launch

Likewise the Three Data Availability Scenarios Are:

1. Robust Data – fully available and applicable data for input into forecasting
2. Incomplete Data – partially available and applicable data for input into forecasting
3. No Data – lacking available and applicable date for input into forecasting

Breaking out the need for primary marketing research input into forecasting in this manner provides a useful framework for deciding which research methodologies might be applicable in a variety of situations. While several are applicable, the following four methodologies are requested often in helping to populate new product forecast assumptions:

1. Qualitative Pre-/Post-Allocation
2. Quantitative Pre-/Post-Allocation
3. Designed Experiments (Monadic Design, Trade-off and Pricing Studies)
4. Qualitative Delphi Technique

figure 5

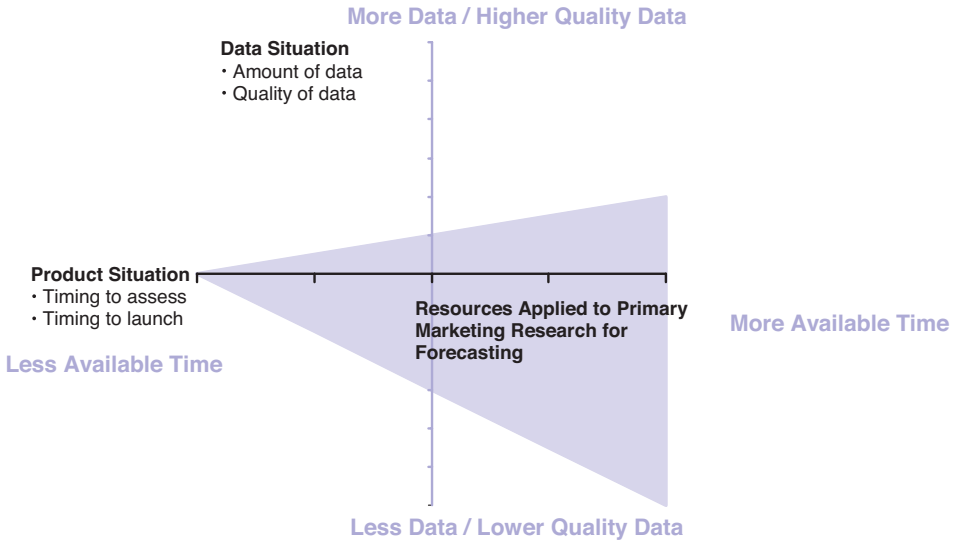
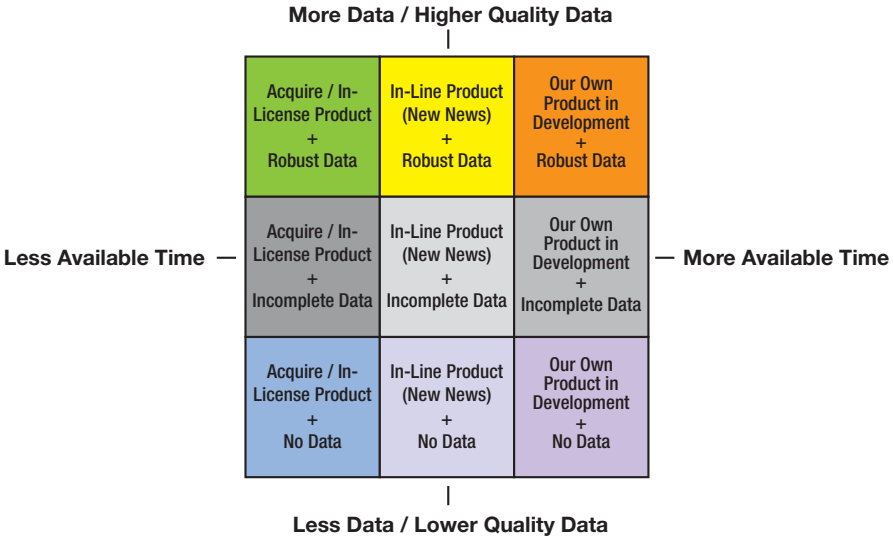


figure 6



Qualitative Pre-/Post-Allocation

This methodology can be described as "a small-scale MR study to assess marketplace receptivity to new or existing product." This is done via asking respondents, in-person (face-to-face or telephone), what they currently do (physicians in terms of prescribing and patients in terms of therapy), then asking them to review a profile describing the new product's performance and how their practices might change with the potential availability of this new therapy. Because of the personal time commitment of the respondent, honoraria is typically higher than in other forms of research and therefore sample sizes are typically much smaller than the other forms of research. The timing for this type of research project can be as little as 3 weeks from start to finish and rarely takes more than 6 weeks. A key advantage of this approach is that it allows all members of the forecast team to hear the rationale or reasons for use or non-use of a product. This is especially helpful if the forecast is for a product in a new treatment area for the company. The biggest drawback is that even with the best moderation, there is significant potential for overstatement to estimated use of the product, in two forms. First, there is the potential for respondents to overstate their estimated product use due to not wanting to disappoint the interviewer in the discussion. Second there is the potential for overestimation due to the small sample size in the study not being representative of the universe of respondents they represent.

Quantitative Pre-/Post-Allocation

This methodology is similar to the qualitative pre-/post-study in terms of design. However, it does feature a larger sample (75-150 per cell or specialty) and a structured/closed-ended survey. The survey, typically Internet-based, quantifies treatment approach/algorithms and also assesses receptivity to new product. The large sample enables an analytical linkage between treatment patterns and receptivity plus analysis of subgroups. Due to the larger sample size and impersonal nature of the survey interaction, this approach may be better at providing reliable, projectable assumptions for estimation of share in the forecast. However, respondent tendency to overstate interest in a product (caused by many reasons including, use of share, a measure of preference) can still lead to inaccurate share/use estimations and assumptions into the forecast. This research can typically taker longer that qualitative research when implemented properly (usually four, but as much as eight weeks).

Designed Experiments (Monadic Design, Trade-off and Pricing Studies)

Perhaps the most robust of the methodologies, here we are talking about large (sample = 75-150 per cell or specialty) quantitative primary marketing research studies to assess marketplace receptivity to new product, albeit in a manner designed to limit potential for respondent bias. This approach more thoroughly evaluates the merits and weaknesses of a new product compared to other primary research approaches through the presentation of various scenarios, including worst and best case. The large sample with these studies enables an analytical linkage between treatment patterns and receptivity plus the analysis of subgroups. The methodology has the ability to assess and link target customer (physicians, patients, others) receptivity to a new product to drivers in their decision-making process. Some additional features of this type of research is the ability to link together the responses of different audiences (i.e., physicians and payors) in more realistically assessing the receptivity to a new product. On the downside, this approach is resource-intensive and time-consuming (typically lasting six to 12 weeks). Additionally, the number of possible factors and resulting scenarios does have limits in terms of what one respondent can mentally process.

Qualitative Delphi Technique

This approach attempts to blend the best of qualitative research with the robustness of interviewing respondents more than once. Analytical vigor is also added by having respondents provide their assessment in the context of what their colleagues and peers have to say. Specifically, it is multi-round, iterative research among a specific audience of respondents (usually thought leaders in a topic) to estimate timing and impact of key future events. In pharmaceuticals, this research can help sharpen clinical program focus and to allocate resources effectively. Recruiting is a challenge with this

type of study as it requires "true" thought leaders—up to 20—from a very small universe to begin with. Timing is also a challenge as it takes longer to recruit and execute for more than one round of research. Telephone is the only format for this research given the difficult-to-recruit audience.

This approach also requires significant preparation of stimuli/material for respondents regarding future events and an extremely knowledgeable and facile interviewer, capable of comfortably conversing with the world's thought leaders in a given therapeutic field.

The exhibit below (figure 7) overlays these four possible primary marketing research methodologies with the nine possible research scenarios. Generally speaking, qualitative research can be initiated quickly, and depending upon the scope, completed fairly quickly. Thus, the qualitative pre-/post-allocation methodology is the only one to be in all nine situations. As indicated earlier, with less urgency and more gaps in data there is the potential for building programs of primary marketing research where each study builds on the previous project in terms of population forecast assumptions versus a "one-off" type of assessment.

In summary, the higher stakes that now exist in pharmaceutical forecasting due to slowing industry productivity and accelerating industry consolidation, require significant preparation and resources from forecasters and market researchers alike. Knowing and communicating the steps to building a robust and effective forecast, strategically utilizing primary marketing research is vital to managing the process to a successful outcome. This is best achieved by understanding the specific situation or context in which you are preparing the product forecast and identifying and communicating the most appropriate primary research methodologies to fit that perspective.

For more information, please contact info@mattsonjack.com

figure 7