How Patient-Records Methodology Can Help Overcome Shortcomings of ATU and Syndicated Data

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Advantages of a Valid Patient-Records Approach

A patient-records approach has the potential for providing new and precise information concerning the present market for an existing or planned pharmaceutical product. In a certain context, this approach also can be more cost-effective. A valid patient-records approach might be used to:

- **Assess market growth potential with much more precision**
- **Identify hidden growth opportunities in a new market**
- **Improve forecasting accuracy with respect to costs, revenue potential and profitability**
- **Reduce data acquisition costs associated with new product assessment.**

Disadvantages of Commonly Used Alternatives to a Patient Records-Approach

The information generated by a valid patient-records approach overcomes many of the limitations of other available data inputs, e.g., data from ATU-type (physician perceptual) studies or data derived from syndicated prescribing data.

Physician perceptual studies are routinely used to obtain insights needed for complex strategic decisions. These studies are very useful, but as with all study approaches, they have their limitations. Clarity Pharma Research clients have found that such studies often yield seriously inaccurate estimates because they ask for information for which there is a factual basis, but rely upon the physician's impression as to what the facts are. Requesting of the physician estimates needed to calculate market share is a case in point. Unfortunately, a physician, like any other human, faces the same barriers to complete and accurate recall. Thus, **physician perceptual studies need to be supplemented with a more factually oriented methodology** when the objective is to obtain detailed, accurate factual data, such as market share and complex dosing patterns by patient condition.

Moreover, physician perceptual studies do not permit statistical analysis of the distribution of ***patients,*** including confidence interval estimates of ***patient*** market share. Perceptual studies are restricted to confidence interval estimates of physicians' estimates of patient market share, which is an entirely different concept.

Syndicated prescribing data represent another common data source. These are, of course, factual data, but they tend to be expensive and replete with coverage limitations. Patently, these data have very real advantages, but they also have serious limitations, and can benefit from use of the type of information our procedures can provide. For example, a new or existing product development team is not likely to have available target drug usage data in grams/units (mcgs, etc.) by cross-tabulated criteria, such as drug indication (including off-label indications), or drugs used for concomitant or adjunctive therapy.

Thus, **neither perceptual data nor syndicated data are adequate for certain research tasks**. For example, a product team is not likely to be able to obtain meaningful information about grams of product lost due to drug underdosing, or gains from (and losses to) competitor products due to drug switching. Moreover, to adequately understand a potential market, a product team needs to know:

- **The magnitude and implications of new patient entry with their dosage levels**
- **The change in dosage as the patients "age" within the treatment period and the exit of patients at some specified future time period**
- **Total dosing and daily dosing per patient (a key requirement for accurate forecasting).**

Patient records are uniquely positioned to provide the above information as well as information concerning the *flow of patients into treatment, their consumption of the target drugs while under treatment, and their subsequent exit from treatment*. We suggest that a client's market strategies for an existing or planned product can be considerably enhanced through the incorporation of patient-record information.

A Valid Patient-Records Approach Requires Representative (Random) Samples

Just as pharmaceutical sales representatives have great difficulty seeing certain physicians, research companies have great difficulty in securing study participation of certain physicians, especially when the physicians are asked to extract detailed information from specific patient records. Many of the busiest physicians (those most likely to be heavy treaters of target conditions) are the same physicians who are least likely to participate in a research project that is conducted for purely commercial or marketing purposes. Moreover, those "heavy treaters" who do participate in commercial marketing studies may not be representative of "heavy treating physicians" as a group. Thus, a study perceived to be solely for commercial purpose is likely to result in the participation of a disproportionately low number of "heavy" prescribers/treaters, and either under- or over-representation of important physician/patient segments in the sample.

High levels of study non-participation or under-participation of important patient segments could lead to fundamentally wrong conclusions and resulting errors in market share estimates. This in turn could lead to very costly strategic business errors.

Patient Records from Physician Panels Do Not Permit National Projections

Because the requirement of random sampling from the target universe is not met in physician panel studies, these studies, like studies perceived to be solely for commercial purposes, do not permit statistically derived estimates, including estimates of the distribution of patients and patient segments **nationally.**

Obtaining Representative Samples of Patient Records: A Difficult Task

Obtaining a representative sample of patient records is one of the most difficult tasks in health care research. An advantage of the Clarity Pharma approach is the acquisition of a scientifically valid sample of patient records. Clarity Pharma employs a unique and innovative method for minimizing the type of non-response bias discussed above. This process involves using nationally respected scientists to direct the study. In addition, Clarity Pharma shares a brief report of selected findings of the research with participating physicians, if the client permits and desires. If a report were to be offered, that report would include no proprietary information and would not be disseminated without the client's pre-approval. Physicians are much more willing to participate in a study for a known academic researcher, especially when they receive a research report. Further, the creditability of Clarity Pharma principals in the medical community facilitates such participation. For example, Clarity Pharma President Dr. Jack R. Gallagher has presented scientific papers and

posters at a number of scientific, medical, and market research conferences over the years and has co-authored publications with an international roster of respected physicians and experts in various medical fields.

Clarity Pharma has conducted numerous national studies in which a representative sample of physicians provided detailed requested information from the records of a representative sample of their patients. This informational tool is derived from our ability to obtain unusually precise, unbiased estimates of **actual usage of target drugs** over specified time periods by use of a national probability sample of individual patients.

Key Advantages of Clarity Pharma's Approach

- The Clarity Pharma approach generates a valid, representative sample of physicians and patients, providing unbiased estimators and permitting statistical tests of significance.

- The Clarity Pharma approach provides a detailed picture of longitudinal as well as current treatment because detailed treatment history information is obtained for a random sample of all target patients (usually the last four patients treated for a target condition or with a target drug by a participating physician). This process enables Clarity Pharma to compare various segments of interest over time. For example, recent newly diagnosed patients could be compared with patients who were newly diagnosed one year ago, two years ago, etc.

- Our approach makes it possible to pinpoint with greater precision the reasons for patient discontinuation of a target drug because this approach yields larger segments.

- Our approach makes it possible to evaluate the flow of patients through each titration phase, measuring the discontinuation (dropout) rate along the way.

- Our approach provides a valid database against which future comparisons can be made, and changes in the marketplace detected.

- Our HIPAA-compliant approach makes it possible to obtain more accurate physician perceptual data than is possible with other approaches because the physician is asked to provide, evaluate, or discuss a specific (de-identified) patient, not the typical hypothetical patient as in an ATU-type study.

- Our approach makes it possible to obtain psychographic information, including physician opinion about treatment benefits sought by specific patients or how proactive or reactive a patient is regarding his/her health care.

Clarity Pharma would be pleased to discuss the above and other important advantages to our approach to patient-records studies.