Disadvantages of Commonly Used Alternatives to a Patient Records Approach

Prepared by: Clarity Pharma Research LLC



(864) 579-2115 • information@claritypharma.com

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.

Attitude, trial and usage studies (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's 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 (such as proposed here).

Syndicated 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 (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 <u>flow of patient into treatment</u>, <u>their consumption of the target drugs while under treatment</u>, <u>and their subsequent exit from treatment</u>. 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.

