CREATING MARKET VALUE WITH LATE-STAGE, POST-MARKETING CLINICAL RESEARCH

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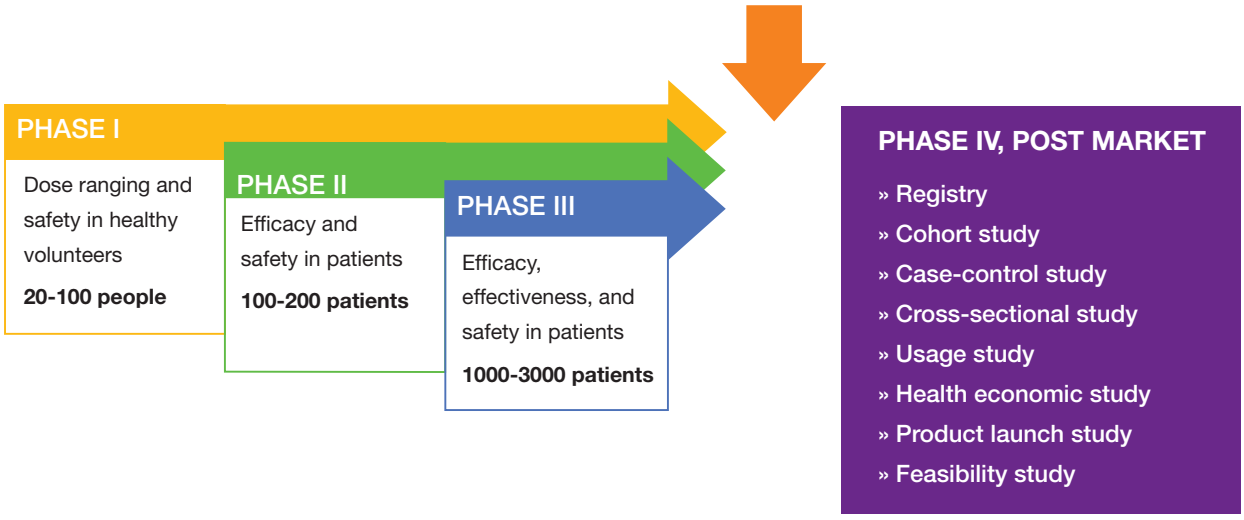
WHAT IS POST-MARKET (PHASE IV) RESEARCH?

Post-market or Phase IV research investigates numerous characteristics or performance factors that are not addressed in the premarket approval (PMA) or 510(k) notification process for pharmaceuticals or medical devices. These include large patient populations, long-term safety, prescription or usage patterns, practical clinical tips, reimbursement, and marketing strategies. When pharmaceuticals or medical devices are granted approval or clearance by the U.S. Food and Drug Administration (FDA), they can be legally marketed. The premarket process is designed to establish the safety and efficacy of a medication or device through "adequate and well-controlled clinical trials."

But the carefully controlled and conducted studies required for approval or clearance do not answer many questions related to a product's widespread, long-term clinical use. Post-market research bridges the gap between approval and clinical practice, providing practical information that increases the value of a product to its maker, healthcare providers, insurers, and patients.

Dietary supplements and nutraceuticals, which do not require PMA approval, can also benefit from post-market research. In a competitive environment that bombards health-conscious consumers with claims, research can help a product stand out from competitors.

Post-market research has a profound impact on product acceptance and adoption rates, as this is the only phase to replicate and understand the real world patient and physician experience with the drug, device, or treatment. Post-market research supports validated claims for your customers within their clinical setting, demonstrates effectiveness, and builds confidence in new treatment options. In addition, it allows the sponsor to generate revenue while gathering important market and product acceptance and usage data.



WHAT CAN YOU LEARN FROM POST-MARKET RESEARCH?

Whether post-market surveillance is mandated or voluntary, it can be optimized to return value on the product's premarket investment. For example, post-market research could answer questions such as:

- What do healthcare providers need to know to weigh the risks/benefits of this product?
- Which patients will benefit most?
- What clinical tips help minimize the risks and optimize the use of this product?
- How does this product compare with competitors in terms of safety, effectiveness, and tolerability?
- How does this product perform in concert with other medications or treatments the patient may be receiving?
- What is the product's value proposition for payers?
- How does the product save time or money?
- How does the product affect patient compliance?
- How does the patient rate their experience with the product?
- Is the product meeting expressed or unexpressed needs?
- What refinements would make the product even more valuable?
- What messages resonate most with the product's target audiences?

Answers to all of these questions provide extremely valuable insight to marketers as they develop messaging for physician and patients, training programs, and awareness campaigns.

HOW DO OBSERVATIONAL STUDIES DIFFER FROM RANDOMIZED CONTROLLED TRIALS?

Randomized, controlled trials (RCTs) are considered the gold standard for medical research, as they limit bias, strictly control study parameters (such as inclusion/exclusion criteria and methods), and focus narrowly on specific outcomes. Yet these characteristics make RCTs fundamentally different from daily clinical practice. For example, the small and selective RCT population and extensive inclusion/exclusion criteria, frequent monitoring, and relatively short trial period are rarely indicative of medical practice. Observational studies can be conducted with much larger populations, for longer periods of time, and under actual clinical practice conditions.

There are also cases where RCTs are impossible, unethical, or impractical. Consider surgical procedures, for example. Both the surgeon and patient will know if the surgical procedure occurs, which negates the masking required in RCTs to control bias on the part of the healthcare provider or patient. And RCTs may be impractical for rare diseases with small numbers of patients. Observational studies are also useful in comparing the effectiveness of two already approved products.

WHAT TYPES OF POST-MARKET STUDIES COULD YOU CONDUCT?

The appropriate study design depends on your scientific or commercial objectives, how you plan to use the study results, and your target audiences. Different study designs yield different types of information.

A registry collects uniform clinical data to evaluate specified outcomes for a defined population. The data

may serve scientific, procedural, clinical, economic, or policy purposes. Registries can be national, such as those maintained by the National Cancer Institute, or kept by pharmaceutical or device companies. They are particularly useful when formulating national healthcare policy, or when treatments are changing rapidly.

Cohort studies track a group of people with certain diseases or characteristics over a period of time. They can answer questions about long-term health habits, comparative effectiveness or safety, and quality of care. In cohort-control studies, the cohort of interest is compared with a control group. Cohort studies can be prospective, determining inclusion criteria and outcomes of interest beforehand and then following patients for specified times, or retrospective, analyzing medical databases that collected information for other purposes.

Case-control studies compare patients who have a disease or outcome of interest (cases) with patients who do not have the disease or outcome (controls). These retrospective studies compare how frequently the exposure to a risk factor occurs in each group to determine the relationship between the risk factor and the disease. These studies are good for studying rare conditions or diseases, and allow analysis of multiple risk factors simultaneously.

Cross-sectional studies examine an exposure or outcome of interest in a study population at one point in time. They cannot be used to establish causality, but they may aid in developing risk-management strategies.

WHAT TYPES OF STUDIES SUPPORT PRODUCT COMMERCIALIZATION?

Pre- or product launch studies smooth the introduction of new products. Companies succeed by putting the right product, at the right price, in the right place, at the right time. Product launch studies shape these classic 4 P's (product, price, place, promotion) into a workable strategy. The information gathered in product launch studies can be used to educate physicians, payers, sales people, and patients. Often principal investigators or key opinion leaders are involved, because of their expertise and peer-to-peer credibility. Input from healthcare providers and patients may also influence the messages designed for target audiences at product launch.

Usage studies examine prescribing patterns and explore the users' rationale for selecting one product over another. They may also measure how well clinical practice guidelines are implemented in given settings. That, in turn, may determine what types of research or training are necessary to implement best practices.

Health economic research analyzes the costs associated with health and disease, the benefits of prevention and treatment, and the efficiency of health systems.

Feasibility studies explore technical refinements or new uses for a product. These typically small studies identify the steps that would be necessary to ready a device or procedure for commercialization. Often they bridge the gap between the laboratory or research setting and clinical practice.

HOW DO Post-Market RESEARCH STUDIES INFLUENCE BUSINESS DECISIONS?

The results of post-market research arm business leaders with information to make decisions about the marketing strategy and overall direction of new products. In many cases, post-market research helps to more specifically define target segments and product messaging so that marketing dollars are spent more efficiently.

In some cases, when products perform poorly in post-market research, results will lead decision makers to cease marketing activity and focus resources on other, more lucrative projects.

Often, when a new drug or device performs strongly in post-market research, stock value may increase, which will position the entire company for greater success.

KEY POINTS

Post-market research adds value by:

- Boosting physician and patient confidence in new drugs and devices.
- Developing physician product champions and KOLs to represent and endorse your product/treatment publicly to your target audience.
- Building on the premarket studies that established efficacy and safety with analysis of larger patient populations, longer-term safety, prescription or usage patterns, practical clinical tips, reimbursement, and marketing strategies.
- Facilitating new product introductions and supporting awareness and education for physicians, payers, sales people and patients.
- Helping a product stand out from its competitors and understanding how product choices are made.
- Providing information in some cases where randomized, double-blind, controlled trials are impossible or impractical.
- Analyzing the costs associated with health, disease, prevention and treatment.
- Exploring the feasibility of new products and procedures, or refinements to existing products and procedures.
- Allowing the sponsor to generate revenue while gathering important market and product acceptance and usage data.

If you have a post-market study under consideration and would like to engage a dedicated partner, contact Nexus Biosciences at:

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Gliklich RE, Dreyer, NA, Leavy MB, eds. Registries for Evaluating Patient Outcomes: A User's Guide. AHRQ; 2014. https://www.ncbi.nlm.nih.gov/books/NBK208632/. Accessed May 25, 2016.