

# If You Build It, Will They Come?

## Phase IV Recruitment

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Pharmaceutical manufacturers are increasingly engaging in Phase IV initiatives, where goals include better product awareness or documenting health and patient-reported outcomes. Such trials typically require large numbers of patients to provide adequate geographic representation and to accurately measure inter-physician variability. Patients are recruited in large numbers and measured parameters being studied tend to be less intensive and more focused around specific objectives that can reasonably be collected in the primary care setting.

- availability of patients who meet the inclusion criteria, and
- patient willingness to participate.

In Phase IV studies, however, physician interest and involvement in the trial is as important as patient availability. Because Phase IV studies vary in design (*i.e.*, they are not usually randomized, blinded, crossover trials), factors affecting patient recruitment patterns need to be analyzed on a case-by-case basis. A number of factors impact recruitment (Table 1).

In order to shed some insight into patterns of patient recruitment, Phase 4 Health Inc (P4H) analyzed five recently conducted programs (Figure 1).

In all cases, the patient recruitment rate accelerated within two to three months of study initiation, likely due to physicians' gradually becoming more familiar with the study processes until a routine was adopted. This factor may be a particularly important consideration when launching studies for products that have peak patient recruitment periods and that are affected by seasonal factors, as is the case with asthma or attention deficit hyperactivity disorder products.

Ideally, the study should begin two to three months prior to peak market potential, so as to allow physicians' complete familiarity with the study to coincide with larger patient pools.

As would be expected, recruitment in specialty areas, such as Alzheimer's (Program 2) occurs at a much

Table 1

### Factors affecting physician recruitment in Phase IV trials

- Competing interests for physicians' time
- The availability of in-office resources
- Physician interest
- The season of recruitment
- The study duration
- Planned tactics or compelling arguments for maintaining the study "top-of-mind" with physicians

While recruitment issues have been exhaustively studied in Phase III trials, relatively little has been documented about recruitment patterns in large Phase IV trials. Phase III trial recruitment is primarily affected by two key factors:

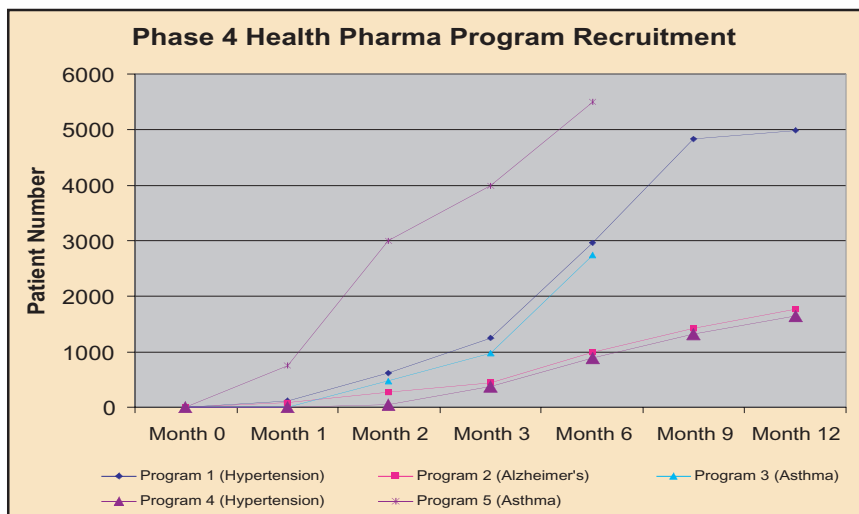


Figure 1. Patterns of patient recruitment.

slower rate than primary market product recruitment for promoted products, such as asthma (Programs 3 and 5) or hypertension (Program 1) products. Interestingly, a non-promoted product with low levels of physician communication, as was the case in a second hypertension product (Program 4), resulted in a decelerated recruitment rate that mimicked specialty area patterns.

The program with the highest rate of recruitment (Program 5) coincided with a product launch and a well-designed program with intensive physician communication and a strong proposition. Excitement was created in the medical community because physicians believed in the scientific merits of the therapy, the value-added features of the program, and the clinical benefits their patients would receive.

Programs launched alongside newly launched products typically result in accelerated recruitment patterns, although reimbursement issues must be considered if access is limited at the time of launch. Physicians may be reluctant to enroll patients in a program or trial if they perceive they will incur an administrative burden or patients will experience reimbursement hurdles on top of adopting a new therapy.

Recruitment is proportional to

study duration and persistence does indeed pay off. Program 1, for example, had a recruitment period of one year, and a full cohort of 5,000 patients was eventually recruited.

Because a wide variety of factors impact recruitment efforts, a careful case-by-case analysis is required. With a keen understanding of recruitment patterns and proper planning for the product and the environment, your program can attract the requisite number of patients. **CPM**

*Phase 4 Health Inc. (P4H) is a leading outsourced commercialization partner to the biopharmaceutical industry. The P4H multidisciplinary team's proven experience and know-how help clients bring products to market faster, and improve their performance throughout their product life.*

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# Russell Reynolds Associates



As part of the firm's growth strategy in Canada, Shawn Cooper, Managing Director and Country Manager of Canada for Russell Reynolds Associates, is pleased to announce the appointment of Bernadette Testani, who will lead the firm's Canadian Healthcare and Professional Services practices as Executive Director.

Ms. Testani brings 12 years of executive search expertise to the firm and was most recently a Partner with another global search firm, where she served a variety of clients within the life sciences and professional services industries throughout North America. Ms. Testani received her B.A. in Administrative and Commercial Studies from the University of Western Ontario.

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