Bridging the Gap Between Clinical and Marketing Initiatives

Phase 4 Health Inc.

By Ravi Deshpande, PharmD

While spending in Phases II and III has an annual growth rate of only 7%, spending on post-marketing clinical research (*i.e.*, Phase IV) is growing at an annual rate of 20%.[1] A number of market pressures have contributed to the increase in Phase IV programs and initiatives. Reasons for this changing perspective include:

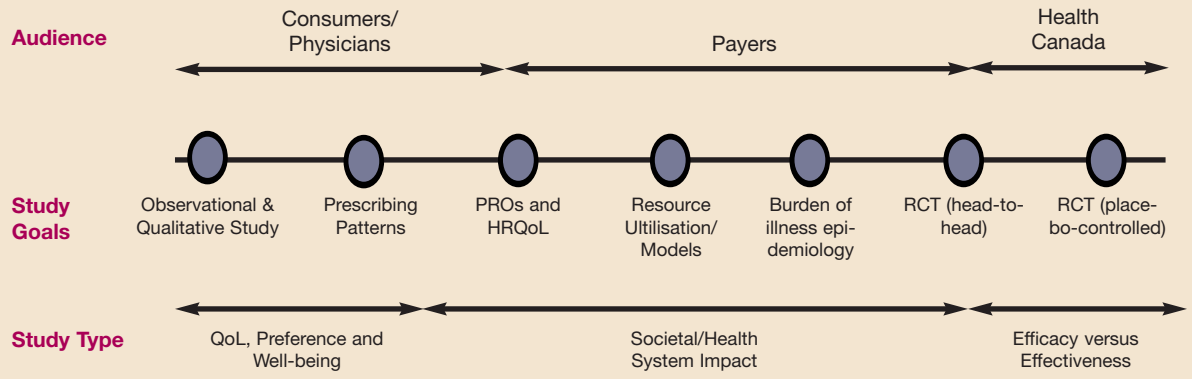
- the dropping rate of new product introductions;
- the increase in commercialisation time;
- the continuing generic erosion rates of brand names;
- the clogging of the development pipelines;
- the overcrowding of therapeutic categories, which have become more competitive than ever before; and
- an increased pressure to demonstrate long-term safety and sound health outcomes, sometimes as a condition of regulatory approval.

The research needed to sell a product is often quite different from the research needed to obtain marketing approval. The goals of classic Phase I to Phase III studies are to demonstrate safety and efficacy (*i.e.*, the product does what the label claims it does). But this is not enough to convince the marketplace. The buyers—physicians, payers, and patients—have questions that are not answered by these studies. For example:

- How does the drug compare to current "state-of the-art" therapy?
- What is the long-term safety of the product? (It is estimated that 300,000 patients would have to be studied to be 95% certain of finding an adverse event that occurs with a frequency of 1/100,000. This is not a possibility in pre-approval trials.)
- What are the economic benefits of using one drug or treatment versus another?

Late phase trials (*i.e.*, IIIb and IV) focus on researching such questions and can add significant

The role of different types of studies and the audiences to which they are most relevant



Abbreviations: PROs-Patient-reported outcomes; HRQoL-Health-related quality of life; RCT-Randomised controlled trials; QoL-Quality of Life.

Source: Phase 4 Health Inc.

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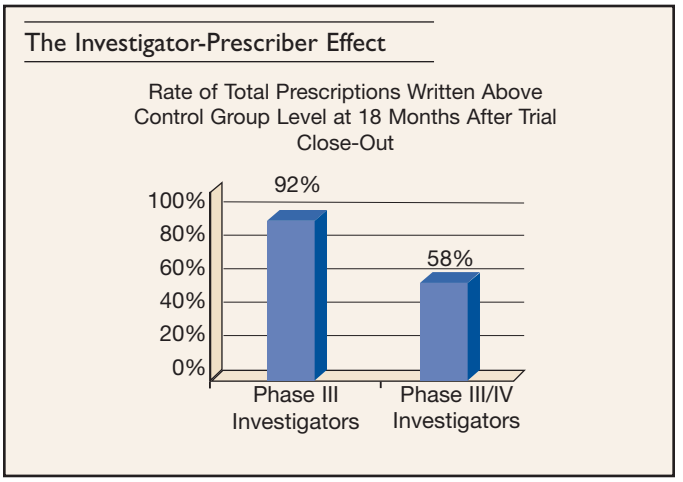

Source: 3rd Annual Phase IV Clinical Trials Conference, September 23, 2002.

new information about the health and humanistic outcomes of using a product. This information is of paramount importance to payers, patients, and physicians. Such studies may provide the distinguishing features of, for example, one antihypertensive versus another. Data from these studies may also add significant new information to the product label, increase the scientific knowledge base, and help educate practicing clinicians on a product's safe and effective use. If disseminated appropriately, these data have the ability to optimise product utilisation and support long-term revenue growth.

Post-approval clinical studies are an important component of any product life cycle management strategy. Savvy marketers are increasingly exploiting the possibilities of Phase IV research to extend knowledge about safety and effectiveness within actual use settings, and to use product positioning against the standard, against new therapies, and against competitors, as well as to prime and test the market.

Phase 4 Health Inc (P4H) is a leading out-sourced commercialisation partner to the biopharmaceutical industry. The P4H multi-disciplinary team's proven experience and know-how help clients bring products to market faster and improve their performance throughout their product life. CPM

Reference
1. CenterWatch Inc Presentation at CBI's 3rd Annual Phase IV Clinical Trials Conference (Tracked over the period 1999 to 2001), Sept. 23, 2002.

ANTIBODY. Simple is better.

A new healthcare communications agency, ANTIBODY, has been launched in Toronto. ANTIBODY is a division of DCC Communications, the Canadian arm of Dentsu, the world's largest agency brand. The principles are James Cran, Director of Client Service, a former drug rep who spent twelve years in PM and Group PM roles with AstraZeneca, SmithKlineBeecham and GlaxoSmith Kline; Bob Shropshire, Managing Director, a 25-year veteran with experience in both consumer and healthcare, and Creative Director Michael Paul, who was a founding partner of the award-winning SMW Advertising.

ANTIBODY'S business strategy is one word: simplify. Explains Cran: "We all know how complicated pharmaceuticals can be, how busy PM's are. We're simplifiers. We have a disciplined process that distills all that information down to core strategies quickly and efficiently." The new agency will put its emphasis on what Cran calls "the forgotten customer", the drug rep. "The rep's importance is being overlooked. There's huge potential for strong share gains with smarter tools." ANTIBODY's approach will also be tough-minded, adds Cran, "It's time we made sure that a competitive message gets through. With the flexibility to handle objections." Bob Shropshire sums up the new effort: "Just like the weather, everybody talks about 'strategic partnership,' but nobody does anything about it. Having an ex-client as the main contact, a guy who's lived their frustrations; the most experienced creative talent in the field, and a business strategy that's aimed straight at the real issues bugging clients, we think ANTIBODY can be the agency that finally delivers on that promise." Contact James Cran at ANTIBODY (416) 929-0528 ext. 224