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How clinical trials make psoriatic disease treatment affordable

05/06/15 | Sarah L. Stewart

Before Archie Franklin began receiving monthly injections of an experimental new drug to treat his plaque psoriasis, the disease covered about 40 percent of his body. Its telltale flakes piled up throughout his home in Indianapolis, and Franklin's regimen of baths, oatmeal soap and Cetaphil offered only moderate relief.

Today, about halfway through a three-year trial for a new biologic treatment from Novartis called secukinumab, the drug's success in treating his psoriasis can be measured by one small, yet significant, number: zero. That's the percentage of Franklin's skin that is now covered with itchy, scaly plaques.



"I've gotten phenomenal results," said Franklin, who has battled plaque psoriasis for three decades.

Since Franklin participated in his first clinical trial 25 years ago, he has been a subject in a variety of studies testing psoriasis treatments, from creams and lotions to supplements. But by far the biggest payoff for Franklin has come from the trials he's entered in recent years for biologic medicines, including the current secukinumab study and a five-year trial he joined for Stelara (ustekinumab) before it gained <u>FDA approval</u>.

By the time a drug reaches pharmacy shelves, thousands of patients have already been taking it for years as part of the FDA's four-phase clinical trials process. The first three trial phases seek to determine the safety and effectiveness of medicines before they are available to the general public. For people like Franklin, who are willing to try a drug before it's been fully proven, clinical trials can offer a low-cost way to gain access to cutting-edge treatments and first-rate physician care.

"It's a great opportunity," said Adele Clark, dermatology clinical studies director at North Carolina's Wake Forest Baptist Health. "Most just want to see if they can find something that will help their psoriasis."



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<u>a pill,</u>

results

according to early trial



Patients must consider a variety of pros and cons before deciding to participate in a clinical trial. But for Franklin, the benefits outweigh the potential negatives.

"I realize there's an intrinsic risk when you participate," Franklin said. "I'm willing to put myself out there."

Reaping the benefits

Without insurance, the retail value of a year's worth of Stelara injections would cost between \$30,000 and \$70,000. (Editor's note: Many, but not all, without insurance qualify for <u>assistance</u> that significantly reduces the cost of biologics.) When Franklin spent five years on the drug during its phase II and phase III clinical trials in the latter half of the last decade, the medication – which dramatically improved his psoriasis – cost him nothing out of pocket. In fact, Franklin even made a little money: Most clinical trials pay a small stipend to compensate participants for their time and travel expenses, generally \$20 to \$50 per visit. Franklin used the cash to buy himself new golf clubs.

Accessing affordable treatment is one reason many participate in clinical trials. Not only do patients have the opportunity to try the latest and greatest new medications at no charge, Franklin said, they also get regular free exams by the doctors and nurses administering the study. For some patients, this may be the only consistent doctor's care they receive.

"I'm constantly under the care of a physician," Franklin said. "There's a real added benefit with having regular contact with a dermatologist."

Perhaps the most dramatic example of this benefit occurred several years ago, during a routine checkup for a study. The doctor noticed a spot that Franklin had assumed was a pimple but which, on closer inspection, turned out to be a basal cell carcinoma – skin cancer – which Franklin promptly had removed.

Another less tangible but equally powerful advantage to participating in a trial is the opportunity to advance the science of treating psoriasis. Without people willing to take part in clinical trials, new therapies that have revolutionized the treatment options for psoriasis patients in recent years would not have been possible, doctors say. Joining a trial has the potential not only to help treat one's own psoriasis but also to help other people, said Dr. April Armstrong, director of clinical trials and outcomes research at the psoriasis clinic at University of Colorado, Denver.

"Patients are an essential part of clinical trials," Armstrong said. "They are helping us to gain new knowledge and push the field forward."

Considering the downsides

Not all of the studies that Franklin has been a part of have had overwhelmingly positive results. In the late 1980s, Franklin joined a study that required him to drink three eight-ounce glasses of immune-boosting milk each day.

"It did very little for my psoriasis, but I got an extra chin," said Franklin, who estimates he gained about 15 pounds from the study, with virtually no relief from his symptoms. "It didn't kill me, but it added some weight."

The safety of a new medication is a primary concern for many people considering joining a clinical trial, Armstrong said, and it's easy to understand why, as the very nature of the research implies that the drug's safety and effectiveness are still being evaluated.

Armstrong helps her patients understand the possible risks by showing them data from previous trials for the drug in question, explaining all potentially adverse effects and offering them historical information about medications that are in the same class as the clinical trial drug. Patients should also understand the regulations governing how clinical trials are conducted to help to make them safer, Armstrong said.

"There (are) a lot of safeguards," she said. "Patient safety is the first priority."

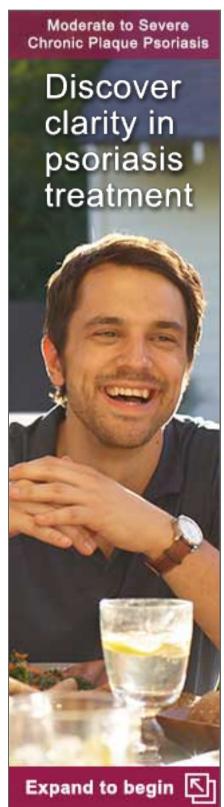
Dr. Steve Feldman, professor of dermatology at Wake Forest, also has confidence in the checks and balances built into the process, from FDA oversight to review boards at study locations. The drug companies themselves are also devoted to patient safety, Feldman said.

"Some of the best academic dermatologists are working at the drug companies," he said.

Beyond safety concerns, another potential downside for patients participating in some studies is the washout period, a span of time when patients must stop taking other medications that could affect the trial. For Franklin, the rebound he experiences with his psoriasis during the washout period is one of the major challenges of participating in studies.







"I had misery for three months," he said of the washout before his current trial. "It was really a frustrating time."

Despite these struggles and the potential risks, Franklin remains optimistic about taking part in clinical trials, more for the ability to contribute to the greater good than even for his own personal benefit. In this way, Franklin is similar to many of the patients Clark sees at Wake Forest, she said, as time and again, they tell her that they simply don't want others to suffer the way they have.

"I just really believe in doing this," Franklin said. "It's how I like to help other people."

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