

by Kristin Butler

“Take one tablet, two times per day, with food.”

We count on physicians to prescribe just the right dose of medication at just the right time to make us well. But long before a doctor signs that prescription a highly regulated research process, sometimes spanning several years, has taken place.

Clinical tests on [experimental drugs](#) are performed in stages. Before a drug is ever considered for human research, pre-clinical studies are done using animal or human cells. At this stage scientists determine a drug’s “pharmacokinetics” – how quickly it is absorbed into tissue and what impact it may have on the body’s metabolism.

Researchers measure a drug’s safety in Phase I studies. Healthy volunteers, usually paid for participating, help researchers establish the safety and tolerance of a drug in humans.

In Phase II a drug is tested on patients who have a particular illness but few or no other health complications. Typically one group receives the investigational drug, which is compared to either a placebo or a standard, approved treatment. (Researchers and patients usually do not know which participants are receiving the investigational drug.) About one-third of experimental drugs successfully complete Phase I and Phase II studies.

At Phase III, a drug is tested on a larger study group to help researchers better understand its benefits and side effects. Dosing intervals, as well as drug interactions, are determined at this stage. Many drugs are put through more than one Phase III study. After Phase III the manufacturer may request an FDA review for approval to market the drug.

Phase IV studies are conducted after a medication is approved for use among the general population. These studies may compare a new drug to others already approved and on the market, or measure cost-effectiveness and long-term benefits against existing medications.

Cox Health Systems’ [Pharmacotherapy Research](#) Division studies a variety of drugs for illnesses ranging from asthma and diabetes, to hypertension and Parkinson’s disease. According to Mark Hecker, Pharmacotherapy director, Cox participates primarily in Phase II and Phase III studies.

Hecker also explains most facilities conducting clinical drug trials have their studies evaluated by an institutional review board. The IRB typically includes professionals from the medical field as well as volunteers from outside the scientific community,

such as legal experts and members of the clergy. The IRB ensures that patient rights are protected, study protocols are clinically appropriate for patient volunteers and that the study is conducted following ethical guidelines. “It would be unethical for us to conduct a drug study on pneumonia patients but not to administer a medication to treat that illness,” Hecker notes. “Our goal is to learn which drug will be most effective.”

Cox is currently participating in a study of a drug, historically used for high cholesterol, to see if it may also prevent stroke. Another medication, prescribed for patients with allergies, is being studied for its effectiveness in controlling asthma. “The more people who are impacted by a particular illness, the greater the interest in finding new and effective ways to treat it,” says Hecker. But he also points out that the U.S. Orphan Drug Act, passed in 1983, encourages drug companies to develop medicines for diseases affecting fewer than 200,000 people in the U.S.

“Both patients and physicians benefit from clinical trials,” says Kathleen Nalley, Cox Pharmacotherapy research nurse. “For example, the investigational drug being studied and the visits – which may include lab tests and X-rays to monitor the patient’s progress – are usually provided to participants at no out-of-pocket expense.”

Another benefit: Physicians whose patients participate in a drug study are able to offer these medications sooner, so it helps them stay on top of the latest treatment options.

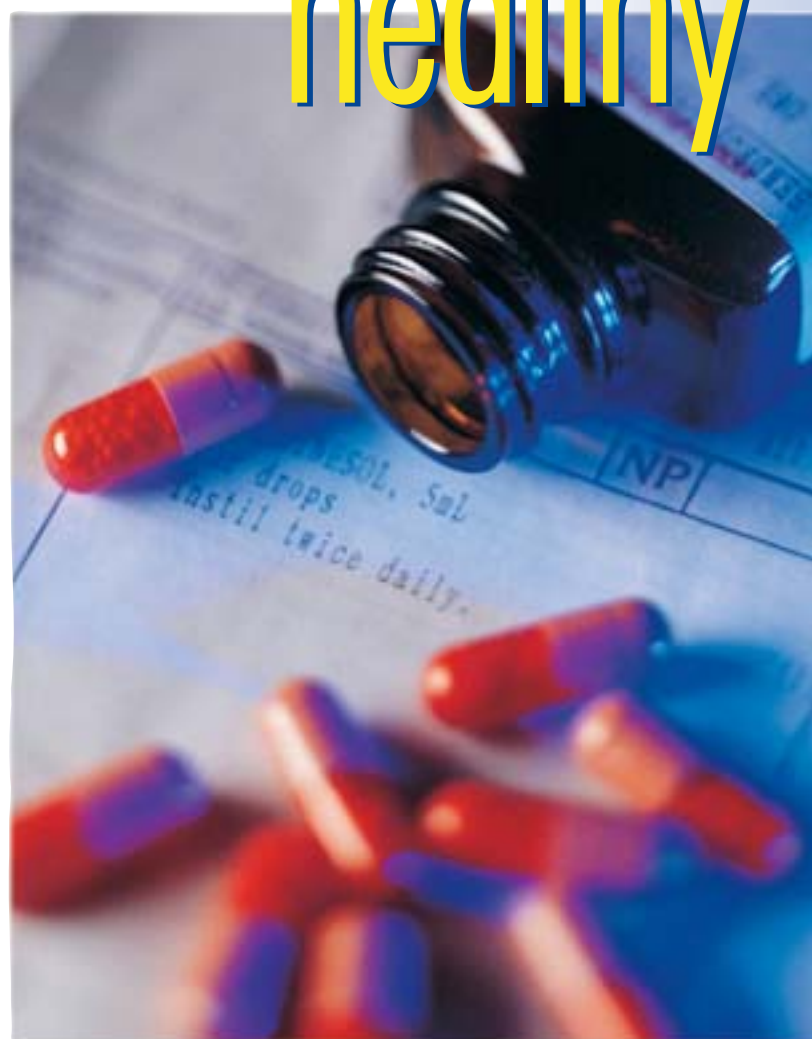
“There is a tremendous potential to help people through clinical trials,” Nalley contends. “And there are many opportunities to participate right here locally through Cox Health Systems.”

For more information about clinical trials being conducted by Cox Pharmacotherapy Research, call 269-6286. ❖

Kristin Butler is a marketing representative for Cox Health Systems.

Sources: CenterWatch Clinical Trials Listing Service; The Columbia Electronic Encyclopedia™, Sixth Edition, Columbia University Press.

A healthy



dose of research

Health Goals



Cox Web site offers

personalized health tools

by Heidi Hartman

Yahoo, WebMD, HealthWeb, Achoo – do you trust a Web site called Achoo.com? If you search the Internet for the key words “health care” you will have more than 4 million sites to choose from. Suddenly, the Internet is not so helpful anymore. Cox Health Systems wants to make it easy for you

to find health care answers for you and your family with [My Health](#) on www.coxhealth.com.

Now you have the opportunity to be proactive with your health and track health-related issues for those you care for. Wouldn't you love to have one place to record all the antibiotics and immunizations your child has had over the last several years?

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minimize them.

From a personal health record to reminders about annual exams, the Cox Web site offers a wide array of personal health

management tools online. Are you at risk for diabetes, osteoporosis, heart disease or a specific type of cancer? We can help you identify risks and ways to improve your odds. You will also be better prepared to speak with your physician if you document your questions and your online research in one place.

You can create personal health diaries for yourself and others in your family. These printable personal health records may include visits with care providers, conditions, medications, allergies, surgeries, immunizations, tests, insurance coverage and basic information such as blood type, emergency contact information and more. You can even set up wireless reminders to receive health information on your cell phone or other device – a handy feature, especially in a health emergency.

You can also track important aspects of your health over time. Trackers include exercise, stress, blood pressure, blood sugar, cholesterol, weight, diet, heart rate, breast self-exam, mammogram, pap smear, colorectal screening, calories burned, body mass index and more.

The Cox Web site allows you to personalize the health manager page so that each time you visit you immediately see news and updates pertaining to your areas of interest. The site is secure and private. The information you enter into this Web site will only be accessible by you. We hope that you will see the value in these new tools, and in sharing the information that you log with your primary care physician or other care providers to enhance communication about your health care. ❖

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HealthSense

the quarterly community magazine of Cox Health Systems

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