SCIENCE'S next wave
www.nextwave.org

Work in Clinical Research—Without a Medical Degree

Joel Rothman graduated from college in 1990 with a bachelor's degree in biology and a burning desire to put his knowledge to work in battling illness and helping people stay healthy. Although he's neither a physician nor a bench scientist, he's fulfilling his career goal as manager of clinical development at Anergen, a small biotechnology company in Redwood City, California. He's also on the leading edge of a new and booming job market for science graduates.

As the biotech field matures, more and more companies are starting to move from the research to the development end of the R&D spectrum. That has created a heavy demand for clinical trials scientists. The problem is that companies don't have time to train such people, and universities have been slow to produce such specialists.

Rothman's entree into the field was typical: He learned about clinical research as a college student while ski patrolling in Doe Mountain, Pennsylvania. "I met a lot of people who worked for pharmaceutical companies," he says. If he hadn't met those people, Rothman might never have considered a career in clinical research. "When you're in college, no one tells you that such a job exists. So you have to find it somehow or know someone who has one," he says. Rothman did both, working at Proctor & Gamble and Genentech before joining Anergen just a few weeks ago.

Careers in clinical research are the subject of the latest "New Niche" alternative career feature on *Science*'s Next Wave (www.nextwave.org), which will begin on 3 October and run until 5 December. In an interactive Web environment, Rothman and others describe their career experiences and answer questions from the audience of the Next Wave.

This is one of a series of pages in *Science* linked to features on *Science*'s Next Wave, the AAAS/*Science* Web site for young scientists (www.nextwave.org). This story highlights an alternative career feature on "Clinical Trials" in the "New Niches" section of the Next Wave beginning on 3 October and running until 5 December.

Scientists working in this area are involved in all aspects of clinical trials and perform duties that range from monitoring the study to managing the data. And there are more open positions than there are qualified people. "There's really no track or educational programming to get someone into those positions," says Stephen Sonstein, a clinical microbiologist at Eastern Michigan University in Ypsilanti. Instead, the key is experience, working in either clinical research or in another area, such as quality control, that will accept entry-level people. Another tactic, according to Rothman, is to go to work for contract research organizations and then move on. But "sometimes even that is difficult," he notes.

Sonstein and his colleagues hope to help make the transition easier with a formal training program in clinical research administration. The program consists of four courses that teach students about drug development, good clinical practices, federal regulations and guidelines, clinical research protocol development, implementation, and monitoring. The program culminates in a 3-month, full-time internship that gives students experience in coordinating and monitoring clinical research. Graduates of the program seem to be successful in the job market. "I went to the Association of Clinical Research Professionals meeting with two of my graduates," says Sonstein. There were 38 companies advertising for over 300 positions. Needless to say, Sonstein's graduates went home employed.

For those who like to travel, working on clinical trials can be an exciting business. Peter Zervos says he spends approximately 20% of his time on the road, visiting the sites where the research is being performed. But he admits that the amount of travel depends on the phase of the project. "In a phase III trial, you may be starting many investigational sites on one protocol, whereas a phase I trial [may require] only one investigational site per protocol," he says.

Even office work can be exciting. "Every day is different," says Rothman. Between phone calls, meetings, and coordinating people within the company, clinical research scientists are always busy. Entry-level clinical research scientists, often referred to as clinical research associates, are frequently involved in monitoring clinical trials. The results of clinical trials are inscribed on case report forms that are filled out by nurses or doctors on the site. "Someone has to verify that the data on those case report forms are real data," says Rothman.

However, a career in clinical research is certainly not for everyone. "You have to be fairly detail oriented," says Zervos. It's a different level of detail than in the research lab. "In the research lab," says Zervos, "you're dependent on your reagents and equipment as well as collaborations with other scientists. Working in clinical trials, you're more dependent on interactions with other people." The job also puts a premium on social skills. "If you need a piece of a report from somebody," and they can't get it to you when you need it, says Zervos, "you'll have to accept, 'I'll get it for you tomorrow.' "

For many scientists, the satisfaction comes from seeing a job well done. Laboratory scientists see the beginning but not the end result of drug development. "It's exciting to see if your drug actually helps people," says Zervos.

But just how important is that science background? "Very," say Rothman and others. "You'll be up there in front of a group of 100 physicians explaining things, and they'll be asking you questions," he says. "If you don't have the science to back it up, you won't give a competent answer."

With the increasing number of new drugs being developed, scientists who have the necessary background and skills to work in clinical trials will be very much in demand. And with the development of new training programs, it should become easier to get that experience. To find out what the needed skills are and how to get that experience, check out the New Niche. It could be the first step on a very rewarding career path.

–Nicole Ruediger

For more information on careers in clinical trials, please go to *Science*'s Next Wave, on the World Wide Web at www.nextwave.org, and click on the "New Niches" button on the home page. There you will find essays by some of the people mentioned in this story, along with resources that will help you get started.