

Little known training in demand

By Monica Chen : The Herald-Sun

Kwami Imani, 35, used to be a bus driver. He could have been a supervisor or gone into conducting trains. But in 2004, he registered for nursing classes at Durham Technical Community College, and then almost on a whim, enrolled in the Clinical Trials Research Associate program.

When he graduates two years from now with CTRA and nursing degrees, he will earn \$35,000 to \$52,000 a year. A year after that, the ambitious Imani said, he'll be able to negotiate for salaries around the 60-grand mark.

As the little-known CTRA program at Durham Tech nears its 10th anniversary, students and teachers are proclaiming it officially a success, and local companies are taking notice.

Clinical trials research associates, working behind the scenes to help drugs move from research level to ready for FDA approval, play a variety of roles. They assist investigators and researchers, monitoring and administering clinical trials of products with human participants and collecting the test results.

Because clinical trials are often the last front before a drug is approved by the FDA, associates' expertise and training have become crucial to biotechnology and pharmaceutical companies.

CTRA at Durham Tech, one of the first such programs in the country, has funneled 99 percent of its students into well-paying jobs, said Director Melissa Ockert in an interview Friday.

After a series of high-profile drug recalls in the pharmaceutical industry, companies in recent years have begun emphasizing the clinical trials step to produce litigation-proof drugs.

As a result, the research associate field has experienced a boom.

"We just cannot get enough qualified people," said David Cooper, vice president of Global Staffing with Quintiles Transnational Corp.

Quintiles' clinical research stage has grown by 25 to 30 percent a year for the past two to three years, Cooper said.

The international contract research organization is the most recent partner with the Durham Tech program, joining the ranks of GlaxoSmithKline and N.C. Biotechnology Center in helping to grow the program.

Quintiles is announcing an annual gift of \$28,400 to the program today.

The money will go toward stipends to students, scholarships and supplement teacher salaries.

Quintiles is hiring 35 research associates a month in the United States, Cooper said, with 40 to 50 percent of those jobs in North Carolina .

"You see a rising tide for these jobs," he said. "Helping the local work force, creating well-paid jobs for local residents, for us is tapping into the local talents supply chain."

CTRA AT A GLANCE

The Clinical Trials Research Associates program at Durham Technical Community College has four tracks.

The associate degree, the longest at 30 months, has a tuition of \$3,108 for in-state students.

The degree is suited for students with no prior experience with science or data-entry and has anatomy and physiology courses, statistics and computer courses. But those with prior science or health care experience, like nurses, could go the shorter route.

Certification programs in research monitoring, data management and study coordinator are 18 months long and range from \$672 to \$756.

Clinical trials research associates help investigators and researchers with pharmaceutical and biotechnology companies monitor and administer clinical trials of products with human participants.

The CTRA program, with classes mostly in the evenings, will be adding a day program in spring 2008 to take an additional 20 students.

This past summer, it added data management to its certificate tracks.

The program has come a long way from its humble beginnings in 1998, when it was founded by Lee Ferrell, a former chairwoman of the advisory committee and the main person to conceptualize the program.

CTRA started solely on state funding with just 20 students.

"When it first started," said Ockert, who has been program director for most of its life, "I literally begged people to take students, give us a chance."

Employers at the time weren't sure an academic program could teach workers the skills, she said.

"We had to prove an associate degree can prepare students to do the work," Ockert said.

Nowadays, the program has 50 students, a waiting list of 10 to 20 people, and companies in the Triangle clamoring for more graduates to come through the academic pipeline.

According to the Society of Clinical Research Associates, a national professional organization, there are now 5,000 certified associates in the country.

Certifications help employers ensure clinical trials are conducted properly and protect against liability.

"The need for clinical research assistants far exceeds what's available," Ockert said.

Ockert, a former research associate herself, has run through the gamut of experiences in the field.

She has been a monitor with pharmaceuticals, traveling all over North America to assess the accuracy of clinical trials.

She has worked up the career ladder, becoming a project manager and working for Durham-based Constella Group, now SRA International, in a government-funded research project.

Like others before the start of the program at Durham Tech, Ockert stumbled onto the field, learning on the job the mind-numbing complexities of FDA regulations and detailed research protocols.

"I struggled trying to learn how to do the work," Ockert admitted. "I'm doing this [program] because I feel very strongly about contributing to the profession."

The Durham Tech program has an associate degree track and four tracks for certifications. It is budget-friendly for people supporting families as well as immigrants who wish to gain a foothold into a stable career.

Associate degree students also work for local companies to gain fieldwork experience after their first year.

"When I started doing the fieldwork, all the lights started going off," Imani said. He's currently working for the Duke Comprehensive Sickle Cell Center.

Imani plans to be a monitor when he completes the nursing degree in 2009. Monitors are their own bosses, he said, and work on a contract basis with different CROs.

"If you have clinical trials and nursing, it's like a one-two punch," Imani said. "You've got the background, you know how to monitor and you know the hospital side."

For other students, like 62-year-old Betty Hobgood, the program was a gateway to a new career as well as a chance to return to a previous love.

Hobgood, who came from a chemistry background, praised the CTRA program recently for its thoroughness in preparing students for the work.

"It has been my rock, my foundation, that I fall on consistently," she said of the program. Hobgood works at Quintiles as a specialist, helping to prep research sites.

Hobgood, who discovered the program in a "fluke," was laid off from her managing job in her late 50s.

"I was thinking, 'What could I do to get my employment skills up?' " she said. "Durham Tech was offering a computer course. The girl sitting opposite me was in the program."

Hobgood declined to give her salary at Quintiles. But according to Salary.com, associates with two to five years' experience command a range of \$50,000 to \$80,000 a year.

For Ockert, the program is more than just another career stepping stone.

"We contribute positively to health care in a way not as obvious as nursing," she said. "We're ensuring safe drugs are out there for people."

"I am very humbled by this industry," she added. "Every day, we learn something new."