Career Alternative: Clinical Trials

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ABBREVIATIONS: CAP = College of American Pathologists; FDA = Food and Drug Administration.

INDEX TERMS: clinical trials; employment.

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As an adjunct professor instructing clinical laboratory science (CLS) students, I'm frequently asked about employment opportunities in the field. Historically, the proclivity of graduating students is to find employment in a hospital setting, but with hospitals under severe fiscal constraint, especially in the New York City area, they are no longer the hiring centers for clinical laboratory scientists (CLSs) that they were in the past.[1,2] Because of this, graduates are forced to find career alternatives in order to utilize their degree.

There are a number of employment opportunities available to CLSs.[3,4] These include:

Technical: Private laboratories; physician's office laboratories; college research laboratories; health maintenance organization and union health offices; government laboratories; state and city health departments; blood banks; veterinary offices.

Non-technical: Inspector; infection control officer; quality assurance officer; safety officer; laboratory management; planning and development; information technology; risk management officer; consultant.

Education: Teaching; administration; mentoring.

Commercial: Marketing; sales; public relations; technical writing and illustrations.[5]

However, a career alternative that has come to the forefront in recent years is employment in a clinical trials laboratory.

What are clinical trials?
Clinical trials laboratories work closely with pharmaceutical companies to assist them in the FDA approval process of new compounds and are dedicated to testing samples procured from patients who are enrolled in phase 2, phase 3, and phase 4 trials, testing the efficacy of compounds being introduced by the pharmaceutical companies. After working in a hospital setting for more than 17 years as a microbiologist, I made the transition five years ago to a clinical trials laboratory and quickly found out that these companies are major employers of CLSs, including graduates with an associate degree as well as a baccalaureate degree (Table 1).

How does the work differ from that of a clinical laboratory?
Clinical trials laboratories perform laboratory testing much

Table 1. Employment opportunities in clinical trials

	Associate degree	Bachelor degree
Laboratory	X	X
Project management		X
Client service	X	X
Quality assurance		X
Information technology		X
Safety officer		X
Business development executive		X
Educational coordinator		X

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like a clinical laboratory but, because of the proprietary nature of the business, there is a high degree of confidentiality. CLSs perform not only basic laboratory testing, but specialized testing as well. A typical clinical trials laboratory includes: chemistry; hematology; coagulation; urinalysis; toxicology; microbiology; immunology; molecular biology; and cellular immunology. Work in this environment is rewarding and offers unique challenges. For example, a clinical microbiology laboratory may have a limited number of antibiotic susceptibility panels to be used on specific pathogens, i.e., gram positives, gram negatives, *Haemophilus sp*. However, in clinical trials, not only are there different antibiotic susceptibility panels for each pharmaceutical company's compound and comparator drug, there may be different panels needed depending on the anatomical site from which a specimen was procured. Jennifer Welsch, supervisor of Infectious Diseases at Icon Laboratories agrees. "With so many different studies ongoing, it is imperative to develop systems that will ensure that the correct antimicrobial panel will be used for the proper study. In a hospital setting, there are set formularies for gram positives, gram negatives, and urine isolates. Clinical trials offer a unique challenge with studies from a multitude of pharmaceutical companies, each with their own compound and comparator drug."

What are some other areas of employment available to CLSs? There are many other employment opportunities within a clinical trials company. These include:

Project management: Project management is another department that employs CLSs. This department follows each protocol awarded to the company from the inception of the study until its completion. A project manager is assigned to each protocol and is responsible for all facets of the protocol from its setup to: working with clinical research associates, sponsors, investigators, data personnel, and study coordinators; reviewing management reports, patient status reports, and analyte trend reports; and examining logs of cancelled tests and abnormal result reports. The project manager is the point person for the study and must have knowledge of all of the tests that are included in the study. A background in CLS is essential in order to troubleshoot any problems that may arise during the study in regard to the laboratory testing. This is an administrative position that many former bench technologists covet as they continue their career in CLS. Terrie Mannix, associate director of project management at Icon Laboratories states, "After working for a number of years as a bench technologist, I was looking for alternative careers in which I could utilize my degree. My position at Icon allows me to use my laboratory experience in setting up protocols, as these protocols have a wide diversity of laboratory tests associated with them."

Client service: Client service personnel act as liaisons between the investigator sites that collect the clinical samples and the laboratory. Their duties include: informing sites on the proper sample to procure for the study; managing supplies for the investigator sites; tracking packages of supplies as well as samples; providing information on the proper packaging of samples; examining turnaround time and stability of samples; amending any necessary patient demographics; and faxing selected reports to the investigators. Client service employs both baccalaureate and associate degree CLSs.

Quality assurance: Pharmaceutical companies routinely conduct audits of the laboratory to ensure quality assurance exists for their protocols. The quality assurance department prepares for the audits conducted by the pharmaceutical companies and is the lead department for inspections by regulatory agencies such as the FDA and CAP as well. Additionally, the quality assurance department, to ensure that the work being performed is of the highest quality, conducts regular internal audits of the laboratory. The quality assurance department reviews all competency records, standard-operating protocols, training records, and validations.

Information technology: Information technology departments offer employment to CLSs who are proficient with computers and programming. Formulation and creation of laboratory worksheets, mnemonics, Levy-Jennings charts, test panels, reference ranges, quality control panels, and instrument interfacing are areas in which a laboratory background is helpful. Customarily, a four-year degree is required.

Safety officer: The safety officer is the individual responsible for the overall safety of the facility. Duties of the safety officer include: performing safety audits, safety lectures, and safety monitors; conducting fire drills; reviewing incident reports and safety related issues; writing the safety standard operating procedure manual; ordering personal protective equipment; establishing a chemical hygiene plan; formulating a waste management program; and coordinating safety meetings. Because the safety officer must be familiar with the laboratory and its various tests, a CLS is qualified for this position.

Business development: Business development executives are responsible for preparing presentations to the various phar-

maceutical companies that detail the spectrum of testing the laboratory offers. They serve as liaisons between clients and the laboratory and help clients reach their goals by generating ideas and solving problems. Additionally, business development executives update clients on trends and market conditions; serve as information resources; provide sales and customer service training; and organize educational support for clients. They interpret a client's requirements and match the client's needs with the laboratory's capabilities for a successful trial. Obviously, knowledge of the laboratory and its testing capabilities is of paramount importance for business development executives. CLSs with a baccalaureate degree are eligible to serve in this capacity.

Educational coordinator: Some clinical trials companies offer internships for students enrolled in clinical laboratory courses. The laboratory may offer these internships either alone or through an affiliation with a local university. The educational coordinator must organize clinical rotations for students; provide educational material where needed; formulate examinations and unknowns; and perform didactic and technical training. The coordinator is responsible for the training and safety of students in the facility. CLSs with a four-year degree and experience in teaching can fill the position of educational coordinator.

What are some advantages and disadvantages of working in clinical trials?

As you can see, clinical trials laboratories offer a number of various career options to the CLS. They offer the unique opportunity for an individual to utilize his/her degree in a number of different areas, all within the same company. However, because these laboratories are not located in primary or tertiary healthcare facilities, some areas of CLS such as blood bank and phlebotomy are not germane to these facilities.

Do clinical trials laboratories offer competitive salaries and benefits?

Many of these companies offer competitive salaries, yearly increases, and performance bonuses; full benefits, such as medical, dental, vision and life-insurance; retirement plans and profit sharing; the availability of different shifts; and advancement up the professional ladder as well as other perquisites, such as night differential and tuition reimbursement.

How does one find out about clinical trials laboratories?

Laboratories that deal solely in clinical trials include Icon, Covance, Quintiles, and Barc, while others such as LabCorp and Quest handle not only clinical trials samples but clinical samples as well. Many of these companies advertise in national publications such as *Advance*; their Web addresses are listed in Table 2.

Table 2. Clinical trials laboratories contact information

Barc	www.za.barclab.com
Covance	www.covance.com
Icon Laboratories	www.iconlabinc.com
LabCorp	www.labcorp.com
Quest	www.questdiagnostics.com
Quintiles	www.quintiles.com

If you are looking for a career alternative, it would certainly be to your advantage to include clinical trials on your list as a rewarding and satisfying career.

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