

Clinical Research

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A. Background

What is a clinical trial?

Source: http://www.hc-sc.gc.ca/english/media/releases/2000/2000_11ebk1.htm

When a drug manufacturer applies to have a new drug approved for sale in Canada, it is expected to show scientific evidence of the drug's safety, efficacy and quality in humans. While the effects of a new drug on people can be measured in other ways -- such as astute observation or anecdotal evidence - a clinical trial is the best scientific approach to providing clear and reliable data.

Specifically, a clinical trial is used to determine whether a drug is safe and effective, what dosages are most effective, and what side effects a drug may cause in people.

In a controlled clinical trial, comparable groups of people receive different forms of treatments. One group may receive the drug being tested, while another group may receive a treatment already known to be effective, or a placebo (an inactive substance that looks like the drug being tested). Once the trial is complete, the outcomes of the separate groups are compared and analysed to determine the effect of the drug.

Who regulates clinical trials? Who runs them?

Source: http://www.hc-sc.gc.ca/english/media/releases/2000/2000_11ebk1.htm

Clinical trials in Canada are most often cooperative projects undertaken by many players including the drug industry, research granting councils, the medical community, the ethics community and the federal government. When a sponsor -- generally a pharmaceutical company -- wants to conduct a clinical trial in Canada, it must apply to Health Canada. Applicants must submit a "protocol" that outlines the objectives, methods and rules by which they will function during the trial. They must also justify that a clinical trial is worth whatever potential risks the drug might have and that the patients will not be exposed to undue risk. Health Canada reviews the application to make sure all the necessary components have been included in the trial and that the scientific methods are sound. The application is also reviewed by an independent research ethics board, for example a hospital review board, that examines the protocols.

It is the researcher's responsibility to maintain the protocols and gather the data.

Different types of clinical trials

Clinical trials are normally done in four phases, each successive phase involving a larger number of people. Phase one studies, often referred to as "first in humans studies", are primarily concerned with assessing the drug's safety. Testing is usually done in a small number of healthy volunteers, who are usually paid for participating in the study. Phase one trials may be conducted in patients when administration of the drug to healthy volunteers is not ethical.

Once a drug has been shown to be safe, it is then tested for efficacy in a phase two study. Phase two trials involve several hundred patients. The patients are usually separated into two groups, which are randomized so that they are as similar as possible in age, gender distribution, and medical history. One group of patients then receives the experimental drug, while a second "control" group receives standard treatment or a placebo. Often these studies are "blinded", so that the patient does not know which treatment he or she is receiving. "Double blinded" studies mean that neither the patient, nor the researchers know who is getting the treatment. This ensures that the data collected will not be affected by the bias of a patient or researcher.

Once the safety and efficacy of a particular drug has been shown, it is then tested on a much larger scale (several hundred to several thousand patients) in a phase three study, to give researchers a more thorough understanding of the drug's efficacy, benefits, and the range of possible negative reactions. Most phase three studies are randomized and blinded, lasting several years. After successfully completing phase three testing, the drug is ready to be reviewed for approval.

Phase four trials are performed after the drug is on the market. These trials relate to the approved indication for the drug and are important for optimizing the drug's use.

Acronyms

- GCPs: good clinical practices
- SOPs standard operating procedures
- CRFs : case report forms
- CRA: Clinical Research Associate
- CRC: Clinical Research Coordinator
- CRPs: Clinical Research Professionals
- ADR: Adverse Drug Reaction
- SAE: Serious Adverse Event
- CIHR: Canadian Institutes of Health Research (supervises clinical trials in Canada)

B. Occupations

1) Clinical Research Associate (CRA) / Study Monitor

- Not a regulated profession in Ontario
- There are various levels of CRA's depending on years of experience (CRA 1, 2, 3)

Role

CRAs monitor investigational sites to ensure both the quality and timeliness of clinical data. They ensure that good clinical practices are followed, that the site complies with regulations and that the study's objectives are met.

Duties may include;

- Monitoring data and conducting thorough source document verification, case report forms (CRFs) and physician records to see that patients are appropriately enrolled and studied, and to ensure that the data they're given matches the data on the patient's chart
- Checking to see that sites are complying with increasingly complex regulations
- Conducting onsite monitoring to verify the protection of participants, accuracy of reported trial data and ensure that the study is conducted in accordance with guidelines
- Selecting qualified investigators
- Obtaining and monitoring Informed consent
- Conducting adverse event and safety monitoring

- Preparing for audits and detecting fraud
- Conducting study qualification, initiation, interim monitoring and close-out visits to assigned clinical sites and completing monitoring reports documenting such visits
- Performing ongoing training of clinical staff including principle investigators, study coordinators, sub-investigators radiology staff etc.
- Reviewing clinical data for accuracy and completeness and resolving discrepancies
- Review case report forms for clarity and consistency with source documents and monitoring queries generated by data management team
- Assuring adherence to the protocol, standard operating procedures (SOP's) etc.
- Performing study drug accountability and review drug dispensing records
- Facilitating and monitoring adverse event reporting
- Documenting detailed monitoring visit reports and telephone communications including site-related problems, resolutions, and actions taken, protocol deviations, study progress and enrollment status
- Participating in the initiation of new investigative sites

Educational Requirements

- Bachelors degree in Life science, nursing, pharmacy, medical etc.
- Courses in clinical research are available through community colleges (i.e., Humber College) and through private colleges (i.e., Kriger Research Centre)

Skills/Qualities

Technical

- Basic computer skills: word processing, internet, email, presentation programs, spreadsheet manipulation and database knowledge
- Specialized computer skills: statistical analysis software

Communication

- Excellent oral and written communication skills

Other

- Previous clinical monitoring and industry related experience (i.e., biotech, pharmaceutical, medical devices etc.) often requested
- Complete administrative tasks, status reports, and computer assignments in a timely manner
- Work with healthcare and sponsor personnel in a variety of therapeutic areas
- Manage groups of people
- Handle multiple tasks, meet deadlines
- Strong organizational, presentation, documentation and interpersonal skills, as well as a team-oriented approach
- Willingness to travel a minimum of 65 percent often required

Typical Employers

- Pharmaceutical / nutraceutical companies
- Medical devices companies
- Biotech firms
- Research centres
- Many ITPs work in the pharmaceutical industry; to work for hospital research centres, often requires an RN license

Average Hourly Wage

\$26.66/ hour (average)

Salaries vary according to such factors such as experience, level of responsibility, seniority, size of company, size of city, etc

2) Clinical Research Coordinator (CRC) / Study Coordinator

- Not a regulated profession in Ontario

Role

- Implement protocols and manage day-to-day operations
- Accurately execute all procedures throughout trial conduction to ensure regulatory and protocol requirements are being met
- Clinical duties vary according to protocol
- Subject recruitment - evaluate participant overall health and study eligibility by review of subjective/objective data; maintain high efforts for maximum patient retention in clinical trials
- Patient scheduling, data collection and database management
- Perform proper source documentation, data collection, drug accountability, lab specimen collection, and lab processing for all trials to maintain high quality data output
- Dispense medication and maintain records
- Assist in physical exams
- collect and process lab work, dispense study drugs, complete CRF
- Interact with regulatory bodies; coordinate with sponsors
- Work closely with investigators, statisticians and other personnel to analyze data and publish findings
- Extensive documentation - case report forms, charts , updates, safety reports submissions to principal investigator etc.
- Prepare for monitoring visits (by Clinical Research Associate)
- Timely 'serious adverse event' (SAE) reporting
- Refer abnormal lab or procedure results to M.D with appropriate follow-up

Educational Requirements

- Bachelor's degree in life science, nursing, pharmacy, medical etc.
- Courses in clinical research are available through community colleges (i.e., Humber College) and through private colleges (i.e., Kriger Research Centre http://www.kriger.ca/krc_canada.htm)

Skills/Qualities

Technical

- Basic computer skills: word processing, internet, email, presentation programs, spreadsheet manipulation and database knowledge
- Specialized computer skills: statistical analysis software

Communication

- Able to communicate clearly in oral and written
- Communicate information in simple terms for the general public
- Read and interpret documents such as computer software and documentation and procedure manuals
- Write routine reports and business correspondence
- Interpret a variety of instructions furnished in written, oral, diagram or schedule form

Other

- Medical terminology
- Regulations and good clinical practices (GCPs)
- Understanding patient recruitment ethics
- Previous clinical trial experience often requested
- Expertise in the area being researched is an asset
- Patient care competencies specific to the trials (i.e., obtaining medical history, vital signs, phlebotomy, ECG experience etc.)
- Strong organizational skills
- Able to function independently within the research environment
- Takes initiative, self-motivated
- Attention to detail, accurate
- Ability to understand and to improve complex processes
- Ability to build partnership, teamwork and collaboration capabilities
- Additional languages an asset
- Excellent people skills (subjects, sponsors, co-workers)
- Strong problem solving skills
- Strong at recruiting trial subjects
- Professional and mature
- Able to multitask
- Time management/efficiency skills
- Safety awareness
- Able to solve problems on a daily basis without direct supervision

Typical Employers

- Pharmaceutical/nutraceutical companies
- Medical devices companies
- Biotechnology firms
- Research centres
- Many ITPs work in the pharmaceutical industry; to work for hospital research centres often requires an RN license

Average Hourly Wage

\$23.72/ hour (average)

Salaries vary according to such factors such as experience, level of responsibility, seniority, size of company, size of city, etc

3) Other Positions in the Field

Data Management/ Bioinformatics, i.e.,

- Clinical Data Managers
- Biostatisticians
- SAS Programmers
- Oracle Clinical Developers, Programmers
- Bioinformaticists

Clinical Support, i.e.,

- Quality Assurance Analysts
- Medical Writers
- Regulatory Affairs Auditors
- Drug Safety Professionals

Scientific, i.e.,

- Biologists
- Chemists
- Research Scientists

C) Labour Market Prospects

- Ontario is home to more than half of Canada's brand-name pharmaceutical and medical devices industries, and almost half of its medical biotechnology industry.
- Major pharmaceutical companies generate their revenues from a few key Brand Name products. When the patents expire on these products, other pharmaceutical companies may produce a generic drug based on the "brand-name drug" which will inevitably lead to a loss of profits.
- In the next few years, many key patents will expire and major pharmaceutical companies (i.e. Pfizer, Eli Lilly, Merck, Apotex, GlaxoSmithKline etc.) will be looking to bring new pharmaceutical products off the laboratory bench and onto the pharmacy shelves. In order to accommodate this, the pharmaceutical industry will transition from pre-clinical research and development (R & D) to clinical trial work. As such, the industry will witness a demand for CRPs (Clinical Research Professionals). Source: <http://www.krctraining.com/D1/dcranew3.htm>
- Other factors at play at the same time are tightening regulatory scrutiny that results in slower processes and higher costs for companies. Corporations tend to respond to this with major structural and organizational changes such as mergers, downsizing and outsourcing to countries where labour costs are cheaper.

D) ITPs in the Field

- Many ITPs have had clinical research experience during their university studies or in jobs hence have the knowledge of types of studies, common statistical tests, data sources and statistical analysis as well as having the skills to organize, implement, and conduct clinical trials
- Clinical research takes place in a medical setting; ITPs have the background to interact effectively in this setting
- ITPs already have considerable clinical training and background education in the sciences (anatomy, physiology, etc.) that provides them with much of the background knowledge necessary for specific research projects. Often ITPs who were specialists are hired for research positions related to their specialty (i.e., internist – research on drugs for diabetics)
- In addition, research positions often require less command of the English language than other occupations. For example, maintaining databases and running experiments typically requires lower proficiency in English than occupations requiring direct patient contact.

E) Links

- Canadian Institutes of Health Research <http://www.cihr-irsc.gc.ca/>
supervises clinical trials in Canada
 - Health Canada Clinical Trials information http://www.hc-sc.gc.ca/english/media/releases/2000/2000_11ebk1.htm
 - Clinical Trials.gov <http://clinicaltrials.gov/>
information about federally and privately supported clinical research in human volunteers.
ClinicalTrials.gov gives you information about a trial's purpose, who may participate, locations,
and phone numbers for more details
 - Thomson Centrewatch <http://www.centerwatch.com/careers/jwads.html>
 - Centrewatch Article – Study Monitors (Clinical Research Associates)
http://www.centerwatch.com/careers/CW1007_cra.pdf
 - Centrewatch Article – Study Site Coordinators
http://www.centerwatch.com/careers/CW1107_crc.pdf
- Kruger Research Center www.kruger.com