Advancing clinical trials in Canada

Sustaining innovation on the global research stage

Canadians are in the enviable position of living in a country that ranks fourth in the world in total number of clinical trial sites. From headache pills to chemotherapies, every medical drug dispensed or administered by a pharmacist, clinic or hospital across the country goes through a stringent clinical trial process. For many therapies that are developed all over the world, this process happens in some of Canada's leading research institutes.

Among the most critical parts of this process are the clinical trials that enable scientists to study a drug's effectiveness, safety, potential adverse side-effects and optimal dosage in humans.

"Without clinical trials, none of the treatments we have now would exist," says Lillian Siu, medical oncologist at the Princess Margaret Cancer Centre, University Health Network, professor of medicine at the University of Toronto. "Emerging science becomes medicine because patients and researchers participate in clinical trials."

"The safety and well-being of trial participants is the utmost priority when designing these trials," says Reginald Dias, head of clinical operations for Bristol Myers Squibb in Canada, one of the world's largest biopharmaceutical companies.

Clinical trials do more than just advance treatments through the research phase. For patients, they provide access to novel treatments that are not yet available.

Wilson Miller, director of the Clinical Research Unit at the Jewish General Hospital in Montreal, says patients who participate in clinical trials tend to get a high standard of care. This is because of trial protocols that call for strict monitoring, precise documentation and are overseen by experts in a particular disease. Wait times for procedures such as scans also tend to be shorter for patients in clinical trials.

"Most importantly, they get access to new drugs sooner. For some patients, this could mean the difference between whether or not they survive their disease," says Dr. Miller.

Mr. Dias notes that most major international pharmaceutical companies conduct a large portion of their clinical trials in Canada. Canadian researchers are known worldwide for their quality and expertise as well as their ability to conduct clinical research in complex therapeutic areas with diverse population bases.

"Canada has the most ethnically diverse population within the G7," says Troy André, general manager of Bristol Myers Squibb Canada. "This helps increase the diversity of the participants in trials, which would otherwise have to be done across multiple countries. And because Canadians are overwhelmingly located in major city centres within each province, travel is less of a burden to participants, which supports enrolment into trials."

A number of other factors have driven strong investments in Canadian clinical trials, says Mr. Dias. These include a world-leading education system, a publicly funded health-care system known for its quality, as well as an extensive and internationally recognized clinical research network that includes 17 medical schools, approximately 40 groupings of academic health-care organizations and about 13,600 researchers – all dedicated to clinical trials in a vast array of fields such as cancer, cardiovascular diseases and rheumatology.

"As the network of research and researchers grows, we find there is smoother alignment and communication across our research network," adds Mr. Dias, whose organization had about 150 active clinical trials across Canada last year and has enrolled approximately 4,000 Canadian patients over the years.

For Canadian researchers, clinical trials provide opportunities to gain early experience with potential new therapies – experience that often leads to new areas of research.

"For example, when the first wave of immunotherapies came into early clinical development, we got involved," recalls Quincy Chu, a medical oncologist at the Cross Cancer Institute in Edmonton. "This collaboration fostered other research ideas, including how we can treat arthritis that arises in some patients undergoing immunotherapy."

Dr. Siu at Princess Margaret says clinical trials also bring benefits at a higher, societal level. A country that advances research builds and sustains innovation and is able to stay competitive on the global stage. "As researchers, we hope that patients will continue to participate in clinical trials, because this is the only way we can move the needle forward."

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ABOUT CLINICAL TRIALS

Clinical trials are carried out in three phases. Health Canada defines each phase as:

- **PHASE 1 -** Tests a new treatment drug on a small group to look at the drug's safety, finds the appropriate dosage range and monitors for side-effects.
- **PHASE 2 -** Focuses on how well a treatment works, checks its safety on a larger group of participants – about 100 or more – and determines the best dose.
- **PHASE 3 -** Compares the drug to commonly used treatments and collects information that will allow the drug to be released and used safely in the market. The trial is also expanded to a group of 1,000 or more participants, to make sure it is still effective and to monitor side-effects.

While these are broad definitions of the clinical trial categories, some elements may overlap. For example, the trial size and focus can differ, such as when studying rare diseases or niche market medicines.