

## The value of clinical trials in Canada

Arthritis Consumer Experts (ACE) has partnered with the Canadian Rheumatology Research Consortium (CRRc) to create a clinical trial education and awareness plan. The CRRc is a national network of rheumatologists that conducts clinical research, including trials of new therapies. The ACE-CRRc partnership's goals are to provide information about clinical trials and how they benefit Canadians and to link people living with arthritis to the broader research community.



A leader in arthritis clinical research in Canada

### Puzzled?

#### Be the missing piece

ACE and CRRc have partnered to create an informational video, brochure and social media outreach program to help people with arthritis become more informed about clinical trials and to connect with the community. The program highlights include:

- ▶ A video featuring an arthritis patient-rheumatologist discussion between Cheryl Koehn, the Founder and President of ACE and Dr. Ed Keystone, the Chairman of the CRRc. It can be found online at <http://bit.ly/jhworkshops>.
- ▶ A detailed brochure on clinical trials that can be found in CRRc member offices.
- ▶ A social media platform committed to community and shared arthritis trials experiences.
- ▶ A channel devoted to research on the Arthritis Broadcast Network at <http://arthritisbroadcastnetwork.org/topic/arthritis-research/>, featuring the latest news and information on groundbreaking research and life-changing discoveries.

### Clinical trials: Here today, gone tomorrow?

Canada's role in clinical trials of new drugs is critical for attracting new research here and improving access to new drugs in the long term. Clinical trials of investigational drugs going through phases I, II, and III (<http://bit.ly/HealthCanadaInformationforClinicalTrials>) are exclusively funded by pharmaceutical companies. In 2010, the pharmaceutical industry invested \$110 billion in research and development globally, of which only \$1.3 billion was in Canada and of that, about \$1 billion was invested in clinical trials.

Clinical trials may be conducted in Canada now, but they are slowly migrating outside the country for the following reasons:

- ▶ There is a lack of (or low) tax incentive and credit programs for industry partners;
- ▶ Canada needs to make changes to clinical trial design to keep up with the advances in rheumatology practice;
- ▶ There is a lack of participant interest as patients have many treatment options and are unaware that drugs lose approximately 10% per year of its effectiveness over time.

An estimated 40% of all clinical trials in the world are conducted in Asia, Eastern Europe, and Central and South America. Sponsoring companies can run larger trials in a shorter time frame in these regions because of their lower cost structure and larger pool of untreated patients.

Clinical trials conducted in Canada offer rheumatologists or "trialists," researchers, and consumers specific advantages. For instance,

Health Canada regulates and authorizes the importation and sale of medications. All clinical trial applications for phase I, II, and III are scrutinized in a review process to ensure the medications under study are safe. Canada has a highly trained and experienced workforce, a good standard of medical care, and a diverse population for researching new therapies.

Every year, Health Canada authorizes approximately 900 clinical trials. Currently, there are 122 studies for arthritis in Canada with an "open" status listed on [ClinicalTrials.gov](http://ClinicalTrials.gov), a service provided by the United States National Institutes of Health. Research sponsors must list their clinical trials on a publicly accessible website if they wish to publish their findings in peer-reviewed medical journals.

#### The decline of clinical trial applications

Statistics from Health Canada's *Therapeutic Products Directorate Drug Submission Performance Annual Report - January-December 2010*.

Year	Number of Clinical Trial Applications
2007	776
2010	596
2011	537

## Dawn Richards: Saying “yes” to clinical trials



To find out what consumers might think of clinical trials, ACE spoke with Dawn Richards, a person living with rheumatoid arthritis (RA). Dawn was diagnosed with RA in late 2006 as a result of extreme swelling, pain, and stiffness in her hands, and eventually her feet. Her rheumatologist assigned her an aggressive treatment plan that included a NSAID (Arthrotec®), hydroxychloroquine (Plaquenil®), and methotrexate injections.

**ACE:** Would you participate in a clinical trial?

**Dawn:** I would participate if my disease worsened and other currently available treatments were not an option for me, or if my rheumatologist thought I would do best on a trial medication.

**ACE:** As a person with RA, what do you expect from a clinical trial?

**Dawn:** I want to have confidence that the trial is being well run according to regulations, managed, monitored, and supported properly to ensure the safety and quality of my experience, as well as ensure the integrity of the trial data that is gathered. I want to feel positive about my participation and that I’m contributing to my own health and welfare, and to others’. I would feel privileged to be one of the first to try a new treatment.

**ACE:** What aspects of a clinical trial would you consider to be vital for its success?

**Dawn:** The clinical trial has to give hope and benefits to my health and me. Open communication between participant and researchers is important. I need to feel

comfortable with all the clinical trial protocols and expectations of me as a participant. Researchers must provide me with a point of contact, timeline, dosage information, and information on accessing facilities and post-trial follow-up.

**ACE:** Do you see recruitment pamphlets for clinical trials in your rheumatologist’s or physician’s office?

**Dawn:** I do not see any in my rheumatologist’s office even though he is part of a facility that participates in clinical trials. I do know that my rheumatologist approaches patients and would approach me if he felt a clinical trial will be of interest to, or would benefit, me. I think educating patients about trials is important.

**ACE:** What do you think is the future of clinical trials in Canada?

**Dawn:** In regards to rheumatology, I think some patients may not be participating because they are doing well on their current medications. But if we don’t have trials, Canadians with arthritis who are not doing well won’t have access to potential “breakthrough” medications like patients in other countries.

## Linda Bennett: An insider’s view on clinical research



Linda Bennett has been the Executive Director at the CRRC since 2004. In addition to over 20 years of clinical trials-related experience, she has worked in public health and community health clinics. Linda is particularly proud of CRRC’s partnership with ACE, its role as a founding member of the Network of Networks (N2) and its participation in the Canadian Trials Summit and the resulting Action Plan.

**ACE:** How do arthritis clinical trials in Canada compare to those in the United States and United Kingdom?

**Linda:** We all face similar challenges. In countries where patients have access to care and medications, current study designs and entry criteria make it difficult for broad participation. A decrease in arthritis clinical trials has grave implications for patients, affecting market access and the integration of new treatments into the standard of care.

**ACE:** Why is the Canadian arthritis clinical trials environment at risk?

**Linda:** Over the last 18 months, several key clinical trial sites have closed due to challenges maintaining their clinical trials infrastructure. Clinical trials in rheumatology are complex and require experienced staff and a substantial amount of time and effort. Like the manufacturing industry, the clinical development of new medicines is being managed on a global basis

with work outsourced to third parties in regions with lower cost and larger populations of patients seeking treatment within a clinical trial.

**ACE:** How and why should Canada improve?

**Linda:** Research really does define and shape best practices in patient care; it informs both disease management and prevention. The arthritis community should create a very detailed clinical research website to educate and provide a point of access for the public. The partnership between ACE and CRRC is valuable for engaging the public in all aspects of research from setting the research priorities to participation to helping people to understand research results and their integration into patient care.

*ACE offers its sincere thanks to Dawn and Linda for sharing their experience and expertise to help JointHealth™ members, subscribers, readers, and arthritis consumers across Canada.*

# What are clinical trials?

A clinical trial is a research study involving patient volunteers aimed at answering specific arthritis treatment questions. Trials are conducted according to a detailed plan (protocol) that meet research standards set out by Health Canada. The protocol outlines the reasoning for the study, the outcomes being evaluated (like number of stiff or swollen joints), which patients are eligible to participate, the schedules of tests and procedures, the medication(s) being tested (including the dosages and timing), study duration and how the results will be analyzed.

Clinical trials are conducted to find out:

- ▶ Whether a new medication or device is safe and effective;
- ▶ How a new medication compares to existing treatments and medications;
- ▶ Which medication is more effective for a particular patient or group of patients;
- ▶ Alternative ways to use an approved treatment to increase its effectiveness, ease of use, and/or decrease its side effects;
- ▶ How a new medication or approved treatment affects different, previously untested populations, such as children.



## Should you participate in a clinical trial?

Patients are encouraged to speak to their rheumatologist about clinical trials before their current treatment stops working. Together, patients and researchers can build a streamlined and effective trials environment. As with most treatment therapies, clinical trials have their own benefits and risks.

Below is a table of what to consider before participating in a clinical trial.

### Pros

- ✓ Exclusive access to experimental therapies for free, which is useful if you are unresponsive to current therapies.
- ✓ Expert medical care and attention beyond that given by your own healthcare team.
- ✓ Close monitoring of benefits and side effects can help you detect other health issues.
- ✓ You will feel satisfaction knowing you contributed to improving the health of future generations.

### Cons

- ✗ Your arthritis may not improve and you may experience side effects from the medication under study.
- ✗ Some clinical trials are time consuming and require you to undergo complex medical tests, such as blood tests.
- ✗ If the clinical trial is a single- or double-blinded randomized trial, you may not receive the experimental therapy.
- ✗ You may be required to adjust your lifestyle for the study, such as changing your diet or routine.

## What questions should you ask your doctor before you sign up for a clinical trial?

- 1 What is the main purpose of the study?
- 2 Does the study involve a placebo, new, or current treatment?
- 3 How will the treatment be administered?
- 4 How does the treatment work?
- 5 How long is the study?
- 6 What do I have to do?
- 7 Are there any published study results regarding this treatment?
- 8 What does it cost me to participate? Will my insurance cover these costs?
- 9 Will I be reimbursed for my travel expenses?
- 10 Will I be able to visit my own doctor?
- 11 Can I keep using the medication after the study? How much will this cost?
- 12 Can anyone find out if I am participating in the study?
- 13 Will I receive follow-up care upon completion of the study?
- 14 What will happen to my medical care if I stop participating in the study?
- 15 Do the collaborators have any financial or special interest in the clinical study?
- 16 Are researchers and their staff trained and experienced in clinical research?
- 17 Are there any other tests involved?
- 18 How many people are recruited?
- 19 Who are the sponsors?
- 20 How do you monitor participants?
- 21 Would you participate in the study?
- 22 What are the risks and benefits to me?

## About Arthritis Consumer Experts

### Who we are

Arthritis Consumer Experts (ACE) provides research-based education, advocacy training, advocacy leadership and information to Canadians with arthritis. We help empower people living with all forms of arthritis to take control of their disease and to take action in healthcare and research decision making. ACE activities are guided by its members and led by people with arthritis, leading medical professionals and the ACE Advisory Board. To learn more about ACE, visit [www.jointhehealth.org](http://www.jointhehealth.org)

### Guiding Principles

Healthcare is a human right. Those in healthcare, especially those who stand to gain from the ill health of others, have a moral responsibility to examine what they do, its long-term consequences and to ensure that all may benefit. The support of this should be shared by government, citizens, and non-profit and for-profit organizations. This is not only equitable, but is the best means to balance the influence of any specific constituency and a practical necessity. Any profit from our activities is re-invested in our core programs for Canadians with arthritis.

To completely insulate the agenda, the activities, and the judgments of our organization from those of organizations supporting our work, we put forth our abiding principles:

- ACE only requests unrestricted grants from private and public organizations to support its core program.
- ACE employees do not receive equity interest or personal "in-kind" support of any kind from any health-related organization.

- ACE discloses all funding sources in all its activities.
- ACE identifies the source of all materials or documents used.
- ACE develops positions on health policy, products or services in collaboration with arthritis consumers, the academic community and healthcare providers and government free from concern or constraint of other organizations.
- ACE employees do not engage in any personal social activities with supporters.
- ACE does not promote any "brand", product or program on any of its materials or its website, or during any of its educational programs or activities.

### Thanks

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Arthritis Research Centre of Canada  
Arthrite-recherche Canada

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ACE does not promote any "brand", product or program on any of its materials or its website, or during any of its educational programs or activities.

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