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.

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, 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


<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Clinical Trial Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>776</td>
</tr>
<tr>
<td>2010</td>
<td>596</td>
</tr>
<tr>
<td>2011</td>
<td>537</td>
</tr>
</tbody>
</table>

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.
Dawn Richards: Saying “yes” to clinical trials

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.

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.

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Exclusive access to experimental therapies for free, which is useful if you are unresponsive to current therapies.</td>
<td>✓ Your arthritis may not improve and you may experience side effects from the medication under study.</td>
</tr>
<tr>
<td>✓ Expert medical care and attention beyond that given by your own healthcare team.</td>
<td>✓ Some clinical trials are time consuming and require you to undergo complex medical tests, such as blood tests.</td>
</tr>
<tr>
<td>✓ Close monitoring of benefits and side effects can help you detect other health issues.</td>
<td>✓ If the clinical trial is a single- or double-blinded randomized trial, you may not receive the experimental therapy.</td>
</tr>
<tr>
<td>✓ You will feel satisfaction knowing you contributed to improving the health of future generations.</td>
<td>✓ You may be required to adjust your lifestyle for the study, such as changing your diet or routine.</td>
</tr>
</tbody>
</table>

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.jointhealth.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.

Thanks
ACE thanks the Arthritis Research Centre of Canada (ARC) for its scientific review of JointHealth™.

Acknowledgements
Over the past 12 months, ACE received unrestricted grants-in-aid from: AbbVie Corporation, Amgen Canada, Arthritis Research Centre of Canada, Bristol-Myers Squibb Canada, Canadian Institutes of Health Research, GlaxoSmithKline, Hoffman-La Roche Canada Ltd., Janssen Inc., Pfizer Canada and Takeda Canada Inc. ACE also receives unsolicited donations from its community members (people with arthritis) across Canada.

ACE thanks these private and public organizations and individuals.

Disclaimer
The material contained in this or any other ACE publication is provided for general information only. It should not be relied on to suggest a course of treatment for a particular individual or as a substitute for consultation with qualified health professionals who are familiar with your individual medical needs. If you have any healthcare related questions or concerns, you should contact your physician. Never disregard medical advice or delay in seeking it because of something you have read in any ACE publication.