











## Canadian Institutes of Health Research (CIHR) Institute of Cancer Research (ICR)

## **Clinical Trials**

One of the original strategic priority areas identified by the CIHR Institute of Cancer Research (ICR) during the initial planning and consultation process was Clinical Trials. The institute convened a working group meeting, followed by two teleconferences, to decide how ICR could have an impact on facilitating the movement of novel therapeutic agents from the laboratory to pre-clinical and phase I and II clinical trials. It is currently very difficult for new drugs, discovered in academic settings, to make their way through pre-clinical and clinical testing into patient care. Bottlenecks exist at many levels including access to compound libraries, drug formulation, animal toxicology and initial Phase I and II testing. Only large pharmaceutical firms have the resources to fund the entire process of drug development. The result is that promising agents discovered by academic researchers may be discarded because they cannot be adequately tested. The ICR Working Group recommended that the term clinical trial be defined as any controlled intervention research with outcomes related to cancer, including prevention, palliation and risk education/management and it was agreed that the scope would not be limited to therapeutic interventions.

The Clinical Trials Group (CTG) of the National Cancer Institute of Canada (NCIC) is Canada's foremost group that develops, conducts and analyses national and international multi-centre trials of cancer prevention, therapy and supportive care. More than 90 institutions across Canada enrol patients in NCIC CTG studies and, since 1980, NCIC CTG has conducted more than 170 phase I or II studies that included more than 3,400 patients. In addition to Canadian-based trials, the NCIC CTG leads and collaborates in international clinical trials of cancer therapies.

## **Results and Outcomes**

In recognition of the excellence of the NCIC CTG program, ICR formed a partnership with this group to increase the funds available for cancer clinical trials. In total, ICR has invested \$3.5 million in the NCIC CTG program to support excellent cancer trials across the spectrum of disease.

In addition, in 2004, ICR contributed funds to the CIHR Clinical Trials Program through a priority announcement for applications on non-cytotoxic therapeutic interventions. Eligible interventions included behavioural, complementary and alternative healthcare, natural health products, educational, health services, lifestyle, medical management strategies, pharmaceutical, population health, preventive, psychosocial, surgical and other non-cytotoxic therapeutic procedures. ICR has invested more than \$700,000 to support several projects successful in this competition.

ICR Supported Non-Cytotoxic Therapeutic Interventions Clinical Trials Projects		
Principal Investigator	Institution Name	Project Title
Collet, Jean-Paul	University of British Columbia	The effectiveness of traditional Chinese herbal medicine, accupressure massage and qigong on improving quality of life of cancer patients: A pilot randomized clinical trial.
Levine, Mark	McMaster University	A randomised trial of a shorter radiation fraction schedule for the treatment of localised prostate cancer.
Levine, Mark	McMaster University	The impact of positron emission tomography (PET) imaging in staging potentially surgically resectable non-small cell lung cancers: A prospective, multicenter randomized clinical trial.
Whelan, Timothy	McMaster University	3D conformal radiation therapy for accelerated partial breast irradiation (RAPID) trial.

Dr. Jean-Paul Collet's team are exploring the effectiveness of Chinese herbal medicine, acupressure massage and Qi gong in reducing cancer side effects, such as fatigue, nausea, pain and depression, and to improve the quality of life of cancer patients.

Dr. Levine's project "A randomised trial of a shorter radiation fraction schedule for the treatment of localised prostate cancer" seeks to determine if a compressed four week radiotherapy treatment for prostate cancer which uses a very high-precision radiotherapy technique to direct the radiation to the tumour and away from the healthy tissue could be as effective as the typical eight week radiation treatment, thereby reducing the emotional, financial, and social impact of treatment on men with prostate cancer.

The project entitled, "*The impact of positron emission tomography (PET) imaging in staging potentially surgically resectable non-small cell lung cancers: A prospective, multicenter randomized clinical trial*", also led by Dr. Levine, is examining the use of PET imaging to detect the spread of tumours in pre-surgery staging for patients with non-small cell lung cancer. The use of PET imaging may reduce the number of inappropriate surgeries performed on patients who would not benefit from surgery due to the spread of tumours that may have been missed in current screening processes.

Breast irradiation is given to about 70% of patients over three to five weeks following breast conserving surgery to reduce the risk of cancer recurrence and to prevent the need for mastectomy. Breast irradiation is associated with fatigue, breast pain, skin redness and irritation. Accelerated radiation therapy of one week is delivered only to the surgical site and appears to be well tolerated. Dr. Timothy Whelan's team is examining if accelerated partial breast irradiation delivered in one week is as effective as whole breast irradiation delivered in three to five weeks.

ICR continues to have strong interest in clinical research and has played an important role in the development and promotion of translational research programs led by other organizations.



Institute of Cancer Research

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