MAXIMISING OPPORTUNITIES FOR CLINICAL RESEARCH: THE CENTRE FOR DEVELOPMENTAL CANCER THERAPEUTICS

MA Rosenthal

Centre for Developmental Cancer Therapeutics,
Royal Melbourne Hospital
Melbourne, VIC

Abstract

Clinical research provides laboratory scientists, translational scientists, clinicians and patients with the opportunity to participate in the evaluation of novel therapeutics. However, a significant proportion of clinicians interested in clinical research do not have the administrative wherewithal to conduct such studies. Novel approaches are required to facilitate and enhance clinical research in Australia. In Victoria, a new entity, Clinical Trials Victoria has been established based on the successful model of the Centre for Developmental Cancer Therapeutics, a collaborative cancer clinical research organisation.

Many oncologists seek opportunities to conduct clinical research. Clinical research and clinical trials provide intellectual stimulation, access to new therapies and additional options for their patients. Clinical trial medicine is usually conducted at the highest level of ethical and clinical care.

The effective conduct of clinical research requires substantial administrative effort. Interesting new therapeutics must be sought, protocols written, budgets agreed, contracts drawn up, standard operating procedures established, protocols and plain language statements submitted to ethics committees, adequate data management provided, adverse events reported and accrual achieved. Few Australian oncologists can perform such tasks in isolation. However, specialised administrative support can provide high levels of expertise in non-medical and non-scientific areas. Indeed, good clinical research infrastructure may provide basic scientists, translational scientists, clinicians and their patients with better access to novel therapeutics by establishing efficient, streamlined and successful organisations. Such abilities will be recognised by the pharmaceutical and biotechnology industries and will result in more opportunities to conduct clinical research.

The Centre for Developmental Cancer Therapeutics (CDCT) was formed in 1993 to provide a focus for cancer clinical research in Melbourne. Importantly, the CDCT aimed to establish a centralised administrative hub for its members in order to provide the specialised support detailed above. The CDCT is a collaboration between oncology units at four Melbourne hospitals (Austin and Repatriation Medical Centre, Peter MacCallum Cancer Institute, Royal Melbourne Hospital and Western Hospital) as well as the Walter and Eliza Hall Research Institute and the Ludwig Institute for Cancer Research. The six affiliates established an incorporated, not-for-profit company to conduct clinical research in cancer patients. It has over 120 members including scientists, clinicians, research nurses, data managers, research registrars and administrative staff. The CDCT clinical sites see over 2,500 new cancer patients per year, have conducted over 160 clinical trials, accrue 300 patients per year to the clinical trial program and have an international reputation, particularly in the field of early phase clinical trials. So much so that in 2002, Pharmacia contracted with the CDCT as one of only 10 "preferred providers" in the world to conduct early phase clinical trials of its products.

The CDCT has many strengths of which two will be highlighted. First, it is able to collaborate broadly across a range of disciplines and expertise. Thus, clinical trial design may include the use of functional imaging (PET scans) and translational bio-assays. Furthermore, members of the CDCT have a broad range of interests including clinical trial design, sub-specialistation in specific tumor types and biologic interests including immunotherapy, angiogenesis and apoptosis. Thus, a pharmaceutical or biotechnology company can come to the CDCT knowing that it can provide broad expertise in pre-clinical data evaluation and clinical trial strategies, and might suggest some novel scientific or imaging approaches to "value–add" to the initial early phase trial. Furthermore, the CDCT members can highlight an effective road map for future clinical trial design in order that a novel therapeutic might find its way to market in a most efficient yet scientific manner.

A second strength of the CDCT is the administrative framework provided for its members. The CDCT has a Board of Management, a Scientific Advisory Board and regular meetings between all members. In addition, there are a number of subcommittees including those for bio-informatics and pharmacy. The CDCT has eight administrative staff including a manager, clinical trials team leader, ethics committee co-ordinators, project officers and an administrative assistant. More recently, the CDCT has appointed a half-time director. The clinical trials team leader is responsible for contracts, budgets, developing standard operating procedures and legal issues such as indemnity and insurance. The two project officers have played crucial roles in the development and co-ordination of Clinical Trials Victoria and a mutual acceptance program between four institutional ethics committees. The latter project is an attempt to streamline the process of ethics committee evaluation of multi-centre clinical trials.

The Victorian Government recognised that the CDCT provided a paradigm for a successful, collaborative clinical trials group with a "one-stop shop" approach providing a centralised administrative focus. As a result, $8 million was awarded in a competitive grant process to establish Clinical Trials Victoria (CTV). CTVs founding members are the CDCT (cancer), Neurosciences Victoria (neurosciences), Centre for Clinical Studies (cardiovascular and pharmacology) and Melbourne Health (multidisciplinary). The grant provides funding for infrastructure to the CDCT and CCS but more importantly establishes CTV. In the same fashion as CDCT, CTV is a not-for-profit, incorporated entity that will provide a "one-stop shop" for clinical researchers and clinical research groups in Victoria. In contrast to CDCT, which is entirely cancer-based, CTV will provide such support for any medical discipline and any therapeutic agent or device.

CTV will act as a service company for clinical researchers, providing clinical trial support, marketing, training and education, quality assurance, database management (bioinformatics), regulatory advice, legal and contractual support. CTV will establish strong links with sources of new therapeutics including the Victorian College of Pharmacy drug development program and Bio21, and will aggressively market Victoria as a site to conduct clinical research.

The degree to which a clinical researcher uses CTV clearly depends on experience. Thus a mature organisation such as the CDCT will mainly benefit from CTV providing a strong marketing of the CDCT at a national and international level. This will provide

opportunities for the CDCT through new liaisons with pharmaceutical and biotechnology companies. In contrast, novice clinical researchers may seek assistance with protocol writing, statistical advice, contracts and the like. CTV will encourage new collaborations between clinical researchers and provide the necessary infrastructure to assist the conduct of clinical trials.

In conclusion, conducting clinical research with new therapeutics is an exciting, stimulating and rewarding component of an oncologist's work. Access to such opportunities is made significantly easier through collaborative networks and the provision of specialised administrative support. The CDCT is one successful example of such an organisation where the day-to-day administrative detail is taken out of the hands of clinical researchers, leaving them to focus on what they wish to do: clinical research.

The establishment of CTV moves this philosophy one step further. CTV will implement the CDCT paradigm for all clinical researchers whatever their medical speciality or area of interest. CTV will provide centralised administrative support to all clinical researchers, irrespective of their experience. As a consequence, clinical research in Victoria will become more streamlined, efficient and successful.