

The past twelve months has seen the introduction of the European Clinical Trials Directive and the local implementation of national governance guidelines. Despite these challenges, the NICCTU has continued to expand and develop its cancer clinical trials program through participation in a number of national, international, investigator-led, and commercial trials. Unlike other centres, the NICCTU has not reported a downturn in trial activity (including patient accrual) post May 2004. During the year, 257 patients were randomised to a total of 54 clinical trials: 204 to oncology trials (36 trials open for accrual) and 53 to haematology trials (18 haematology trials).

The NICCTU has an increasing focus in phase I and early phase II clinical trials, with access to novel agents obtained from Cancer Research UK and the pharmaceutical industry. This activity is supported by a pharmacokinetic/pharmacodynamic laboratory and expertise gained through further senior clinical and scientific appointments. Clinical research nurses continue to be trained through links with the U.S. National Cancer Institute.

At the same time as reviewing the remaining hospital sites funded by the HRB, the international panel of experts will also conduct a review of the Planning Grant awarded to the Irish Clinical Oncology Group (ICORG) in Dublin and the Clinical Research Support Centre (CRSC) in Belfast. This two-year planning grant worth €1 million was awarded jointly by the HRB and the R&D Office in Northern Ireland in 2003 to fund the

headquarters and statistical advice and data management functions of the All-Ireland Clinical Trials Cooperative Group across the island. A condition of the award at the time was that nine-month and 18-month milestones set by the panel would be reported to both funders and reviewed by the panel. The nine-month report was submitted by ICORG and CRSC in early 2004 and reviewed by the panel.

INFORMATION TECHNOLOGY

Professor Donal Hollywood, Chair

TELESYNERGY®

A new TELESYNERGY® link was set up at St. Luke's Hospital and was used for a teleconference with cancer specialists at the King Hussein Cancer Center (KHCC) in Amman, Jordan. Secretary of Health and Human Services Tommy Thompson and Andrew von Eschenbach, NCI Director and Consortium Board of Directors member, were on-hand for the teleconference. Participants in the teleconference discussed complex and difficult-to-manage patient cases, including an advanced recurrent cancer case. Histology and radiology exchange, plus remote use of the microscope, occurred during the teleconference.

The success of TELESYNERGY® at the two existing locations in the Republic of Ireland has been very significant, resulting in TELESYNERGY® being proposed as the “architecture” for the first national telemedicine development. The existing system at the Academic Unit of Clinical and Molecular Oncology (AUCMO) has enabled

routine weekly tumor boards with Regional Oncology Units at the Midland Health Board (Regional Hospitals at Tullamore and Mullingar), Mid-Western Health Board (Limerick Regional Hospital), and the North-Western Health Board (Letterkenny and Sligo General Hospitals). The tumor boards have enabled the joint multidisciplinary team review of patients presenting with gastrointestinal, thoracic, and ENT malignancies together with the coordination of care requirements for Lymphoma/Transplant patients.

Information Technology Working Group (IT WG) Chair Professor Donal Hollywood was instrumental in the development of the proposal for the development of a national TELESYNERGY® network for Oncology Services in Ireland. Throughout 2004, the IT WG consulted with members of the Cancer Services Unit at the Department of Health and Children (DoHC) Ireland and staff at the Center for Information Technology, National Institutes of Health (NIH) U.S., to clarify development and implementation of the proposed National TELESYNERGY® Network. IT WG members met with the Health Boards Executive (HeBE) IT group and staff from the Cancer Services Unit and IT group of DoHC to discuss the proposed telemedicine development in the context of other national IT projects. Galway and Cork were identified as locations for the first phase of full TELESYNERGY® installations. The Health Boards were asked to determine a location for a potential linked regional oncology centre for a TELESYNERGY® “lite” system. The TELESYNERGY® systems

in Dublin and Belfast were approved for systems upgrades and a cytogenetics display functionality was added to the system at Belfast City Hospital. TELESYNERGY® support teams will be trained on-site and at CIT in Bethesda, Maryland U.S.

In June, Micheál Martin TD, Minister for Health and Children, announced the approval of up to €1 million in funding to develop a National TELESYNERGY® Network for Oncology Services in Ireland.

Cancer Centralized Clinical Database (C3D)

C3D replaces net-Trials, the initial clinical database system, to provide Web-based access to clinical data. An analysis of functionality from an Ireland perspective began during the year, with support from the NCI Center for Bioinformatics. Staff at the AUCMO at Trinity College Dublin together with NCI's Center for Bioinformatics (NCICB) successfully enabled preliminary access to the Web-based application and early discussions with the Irish Clinical Oncology Research Group (ICORG) have commenced.

TELESYNERGY® Activity at Centre for Cancer Research and Cell Biology (CCRCB)

The CCRCB is participating in the CancerGRID project, a UK Medical Research Council-funded (£2.5M) initiative to develop open standards for clinical cancer informatics. CCRCB will develop a collaborative working environment specifically employing TELESYNERGY®. The CancerGRID project team includes medical

oncologists, translational researchers, computational biologists, and software engineers from Belfast and four other leading institutions: Cambridge, Oxford, London, and Birmingham. The aim is to deliver modular, distributed software solutions to four key problems: clinical trial patient entry; randomization and follow-up; storage and analysis of complex datasets; and linking trial and epidemiology data with profiling information.

The CCRCB will appoint a dedicated bioinformatician to support the distributed CancerGrid software developers and establish tools for the rapid localization, access and manipulation of clinical and biological datasets working closely with TELESYNERGY®. CancerGRID will facilitate trials management and future collaboration across international boundaries by delivering a working services-based Grid infrastructure for cancer clinical trials.

CCRCB is involved in collaboration directly with the University of Cambridge e-science centre to develop user interface software that enables communication of complex biological datasets in addition of pathology and radiological datasets using TELESYNERGY®.

The recent £2.3M Cancer Research UK early clinical trials programme grant is supporting vital infrastructure for early clinical trials. TELESYNERGY® will be employed in international investigator meetings and for sharing of translational research datasets, eg. a Belfast-led international phase II trial of velcade in mesothelioma involving 7 centres including The Republic of Ireland, Netherlands, Italy, London, and Scotland.¹

¹ Information for this section was provided in part by Dr Dean A. Fennell, Centre for Cancer Research and Cell Biology.

NURSING

Ms Mary McCarthy, Chair

The Nursing Working Group (NRS WG) finalised its Action Plan to implement a strategy for nursing within the Consortium. The Board of Directors approved the Action Plan in January. The Action Plan and Strategy are posted on the Consortium Web site.

Current NRS WG membership was reviewed and consideration was given to inclusion of nurses from clinical trials and other services areas where appropriate. The WG continued restructuring of the oncology clinical fellowship programme to reflect the current capacity and capability of nursing research.

During 2004, the NRS WG continued to facilitate and assist in implementing educational opportunities, identified under the Consortium, for nurses on the island of Ireland. Educational opportunities included Clinical Trials Training, Pre-Doctoral Fellowship, and the NCI Summer Curriculum in Cancer Prevention. The Fatigue Project Coordinator at St Luke's Hospital, Dublin, attended the NCI Summer Curriculum in Cancer course. Three nurses (1 from the Republic; 2 from Northern Ireland) completed clinical trials nurse training at NCI in the fall. Upon their return, they presented a joint proposal "How to educate staff nurses in clinical setting to comply with protocol."