

related to Barrett's oesophagus and adenocarcinoma of the oesophagus was extended from 2006-2008 to examine the role of the insulin growth factor axis and folate metabolism in the oesophageal inflammation, metaplasia, and adenocarcinoma sequence. Results have been included in poster presentations at the U.K. Barrett's Oesophagus Foundation meeting. Funding is being sought for additional potential studies that will use available biological samples and DNA to investigate genetic variations in nutrient metabolism.

■ UPDATE REGARDING CONSORTIUM SCHOLARS

Dr. Lesley Anderson, NCI Cancer Prevention Fellow 2005-2008, spent the year in the Infections and Immunoepidemiology Branch, Department of Epidemiology and Genetics, NCI, investigating the aetiology of haematopoietic malignancies and classic Kaposi's sarcoma. She produced four peer-reviewed publications in 2007, two published abstracts, and won the J.D. Williamson Prize for best postgraduate medical research at QUB and the Poster of Distinction prize at Digestive Disease Week 2007 in Washington, District of Columbia (D.C.), U.S.

Dr. Amanda Black, NCI Cancer Prevention Fellow 2006-2009, earned a Masters in Public Health (MPH) from the University of Manchester and commenced training at NCI in June

2007. Dr. Black is conducting research on the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial, which is sponsored and run by the NCI's Division of Cancer Prevention, in collaboration with the Division of Cancer Epidemiology and Genetics.

Other Previous Fellows:

Dr. Marie Cantwell, a nutritionist and NCI Cancer Prevention Fellow 2002-2005, is a lecturer in nutritional and cancer epidemiology within the Cancer Epidemiology and Prevention Research Group at QUB. Together with Dr. Anna Gavin and Professor Liam Murray, she secured funding to develop a Northern Ireland colorectal polyp register that aims to determine the impact of a national bowel cancer screening program on the diagnosis of colorectal polyps. In 2007, she continued to collaborate with investigators at the NCI in Bethesda on the Polyp Prevention Trial. Dr. Cantwell is also collaborating with investigators at University College London on nutritional exposures and breast cancer survival in the DietCompLyf Study.

Dr. Peter McCarron, Consortium Fellow in Cancer Epidemiology 2001-2003, is now a professor at QUB. Since completing his Consortium fellowship, he has maintained an ongoing research program in the field of bioinformatics, with a focus on whole genome association analysis.

Dr. Paul Walsh, Consortium Fellow in Cancer Epidemiology 2001-2003, worked throughout 2007 to coordinate research activities at the NCRI.

CLINICAL TRIALS

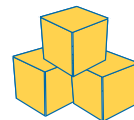
Dr. Anne Cody, Chair

One of the top priorities of the Consortium is to improve patient access to new lifesaving therapies by strengthening clinical trial capacity in cancer centers across the island of Ireland. Since 2001, the Clinical Trials Working Group (CT WG) has worked to support this goal by facilitating funding that enables hospitals in Ireland and Northern Ireland to develop and maintain a clinical trials program infrastructure.

■ ALL IRELAND COOPERATIVE ONCOLOGY RESEARCH GROUP



To drive collaboration among clinical trial centers, the CT WG established ICORG as a central coordinating office for clinical trials and research on the island of Ireland. ICORG is comprised of two offices, the Group Central Office (GCO) located in Dublin and the Statistics and Data Management Office (SDMO) located in Belfast. The GCO fulfills a project management, coordination, and administrative role, while the SDMO provides all monitoring, data management, and statistics expertise.



ICORG has been vital in collaborating with clinical trials cooperative groups in Europe and the U.S., and with the pharmaceutical industry to access new cancer trials for patients on the island of Ireland. A new goal of ICORG has focused on attaining international recognition for clinical research initiatives throughout the island of Ireland. ICORG has played a critical role in opening doors to new cancer trials for patients on the island of Ireland. To this end, the group maintains extensive collaborative relationships with European and American clinical trial cooperative groups and with the pharmaceutical industry. In 2007, ICORG further developed as a cohesive group, resulting in a strong accrual of 747 new patients for clinical trial participation. As ICORG strives to attain international recognition for the island of Ireland's clinical research endeavors, the CT WG finds that the work completed in 2007 has placed the group in a strong position for continued progress and achievement in the years to come. Some key 2007 milestones and results are summarized below.

■ COLLABORATIONS

Cross Border - Interoffice

Building upon the progress achieved in 2006, the GCO and SDMO worked closely on a number of high profile in-house protocols throughout 2007. Both offices coordinated regular face-

to-face staff meetings and teleconferences and ICORG's group statistician attended a number of disease-specific subgroup meetings. In 2007, both offices and the HRB met approximately every six weeks.

International

In 2006, ICORG became a member of the Eastern Cooperative Oncology Group (ECOG). Since then, ICORG has engaged in collaborative research activities with twelve international clinical trials groups, including the Cancer International Research Group, the National Surgical Adjuvant Breast and Bowel Project (NSABP), the Translational Oncology Research Institute, the Breast International Group, the National Cancer Research Network (NCRN), and a number of others. In 2007, collaborative group studies represented approximately 21% of all ICORG studies and the group recruited a total of 302 patients for participation in these collaborative studies.

Pharmaceutical Industry

ICORG's collaborations with prominent pharmaceutical companies remained strong in 2007, resulting in sixteen collaborative studies and 349 recruited patients. The group's partnership with GlaxoSmithKline expanded from ten open protocols to thirteen by the end of the year. Additionally, the inception of a new collaborative relationship with the

Novartis Pharmaceuticals Corporation marked successful industry collaboration for ICORG in 2007.

Patient Accruals

In 2007, ICORG successfully recruited 747 patients, representing a nearly fivefold increase in patient accrual since 2002. Patients participated in a total of 77 studies, with approximately half involved in clinical trials and the other half in translational and tumor banking studies. Breast cancer remained the primary disease area covered by ICORG in 2007, with 42% of all recruited patients participating in breast cancer related studies. Although this percentage represents a slight decrease in breast cancer study participation, from 53% in 2006, new studies in other disease areas, such as gastrointestinal and lung cancer, have achieved a balance that ICORG's international panel was eager to reach.

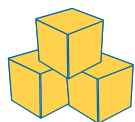
Publications

Two American Society of Clinical Oncology meeting abstracts authored by an ICORG member were published in the *Journal of Clinical Oncology* in June 2007.

■ OPERATIONS

Staffing

2007 marked a milestone year for ICORG in terms of continued expansion



and unified growth. The GCO staff now totals nineteen members, with eight full-time equivalents distributed between fifteen staff members in the SDMO. Notably, a Group Development Executive (GDE) joined ICORG in December 2007. This position is intended to aid the chair and co-chair in developing a cohesive group structure and supporting the administrative development of the disease-specific groups. The first significant challenge facing the GDE was the recruitment freeze imposed by the HSE for the last quarter of 2007, a decision that greatly impacted sites in Ireland. The HRB became centrally involved as an advocate for ICORG, but the freeze was not removed before the end of the year.

Quality

In March 2007, ICORG was audited by NSABP. The U.S. approach differed somewhat from the European Good Clinical Practice audits and led to the inclusion of specific education sessions in NSABP's study initiations.

In May 2007, a dedicated Pharmacovigilance Unit was established at the GCO to address ongoing drug safety concerns, which have become increasingly important in modern clinical practice and in public health. In accordance with the European Union Directive 2001/20/EC, the unit will evaluate the safety of investigational drugs and will notify all concerned members of any information that might adversely

affect the health of patients enrolled in ICORG trials.

Funding Mechanism

In 2007, sites across the island of Ireland moved to a performance-based funding mechanism that involves assigning credits to accruals, follow-ups, and group activities. Payments were made at three stages throughout the year, coupled with projections at the beginning and actual accruals at the end. While this mechanism was initially challenging, it was also a major step forward for ICORG. The group has benefitted from the transparency and fairness of the approach and has found the joint effort in projecting site capacity for accruals and the comparison against actual accruals to be a very useful exercise.

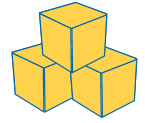
■ NORTHERN IRELAND CANCER CLINICAL TRIALS UNIT

Following the establishment of the Consortium in 1999, the Northern Ireland Cancer Clinical Trials Unit (NICCTU) was formally established to coordinate and promote cancer clinical trials. The Northern Ireland HSC R&D Office provides core funding for NICCTU infrastructure, with additional funding provided through competitive grants awarded by Cancer Research U.K. (CR-UK) and local charitable donations.

The NICCTU, based at Belfast City Hospital, currently coordinates a full

range of first-in-man study phase I to phase IV trials, along with translational, genetic epidemiology, and other studies. The clinical trials conducted by the NICCTU are either initiated by local investigators or serve as part of large multi-center studies sponsored by philanthropic institutions or industry. A team of senior medical, clinical, and haematological oncologists manage NICCTU studies, with the support of an operational director, clinical research nurses, clinical research radiographers, data managers, and administrative staff. On average, approximately sixty NICCTU clinical trials are open for patient accrual at any given time. These trials typically focus on cancers of the breast, ovary, gastrointestinal tract, lung, genitourinary, and haematological malignancies. Pediatric haematological and solid tumor clinical trials are based in the Royal Belfast Hospital for Sick Children (RBHSC). In partnership with ICORG, the NICCTU was able to open a number of local investigator initiated trials across the island of Ireland in 2007. These trials include a randomized phase II trial in advanced gastroesophageal cancer, a randomized trial investigating hypofractionation versus standard fractionation in Spinal Cord Compression, and a phase II trial of the drug Velcade in first- and second-line therapy of mesothelioma.

The NICCTU is also involved with an academic early phase trials unit that maintains a portfolio of CR-UK,



commercial, and local investigator initiated phase I, II, and translational trials. In April 2007, the NICCTU was awarded Experimental Cancer Medicine Centre status, in recognition and support of the Unit's contribution to high quality clinical research in this arena.

In 2007, the NICCTU expanded to include the Northern Ireland Clinical Research Network [Cancer] (NICRNC), which is responsible for the coordination of cancer clinical trial activity throughout Northern Ireland. As one of four U.K.-based national cancer research networks, the NICRNC's portfolio of approximately 250 trials is centrally coordinated through the NCRN in Leeds, England. Annually, the NICCTU recruits approximately 700 patient cases, 8.2% of which involve incident cancers other than non-melanoma skin cancers. Although the NICCTU accrues patients into trials from throughout Northern Ireland, all activities have been based in the CCRCB at QUB. This currently includes the Belfast City Hospital and the Royal Group of Hospitals, which is comprised of the Royal Victoria Hospital and the RBHSC. The CR-UK and HSC R&D Office have jointly funded the formation of the NICRNC to facilitate equitable and convenient access to clinical trials for cancer patients throughout Northern Ireland. Dedicated clinical research nurses have been appointed at each of the four Cancer Units in Altnagelvin Area

Hospital, Antrim Area Hospital, Craigavon Area Hospital, and Ulster Hospital in Dundonald. This clinical research expansion will bring equity of service to patients throughout Northern Ireland and will increase patient accrual and clinical trial capacity and activity.

As part of the CCRCB, the NICCTU works closely with other academic groups, universities, and hospitals and maintains strong national and international links. Key collaborators include ICORG, CR-UK, NCRN, Medical Research Council, European Organisation for the Research and Treatment of Cancer, NCI, ECOG, NSABP, and a variety of other U.S. cooperative groups and biotechnology and pharmaceutical companies.

INFORMATION TECHNOLOGY

Professor Donal Hollywood, Chair

The Information Technology Working Group (IT WG) is committed to building new technological capabilities that promote communication among the three partnering Consortium jurisdictions and to developing enhanced information and sharing methods that benefit everyone. The IT WG also works to facilitate training and education, support the coordination of clinical trials, ensure effective data management, and promote health care delivery systems across the island of Ireland.

■ TELESYNERGY®

The TELESYNERGY® system, developed by the National Institutes of Health's (NIH) Center for Information Technology, is a multimedia medical imaging system that augments the Consortium partners' abilities to collaborate on a variety of projects and activities across the island of Ireland and throughout the U.S.

In November 2007, the TELESYNERGY® Lite system was installed at one site in Ireland, Waterford Regional Hospital. The network now consists of the following:

- A national hub, based at the Academic Unit of Clinical and Molecular Oncology and Trinity College Dublin (TCD), Ireland.
- Four major sites in Ireland at TCD, St. Luke's Hospital, Cork University Hospital, and University College Hospital Galway and one site in Northern Ireland at Belfast City Hospital.
- Two "Lite" systems in Ireland, at Letterkenny Regional Hospital and Waterford Regional Hospital.

By late 2008, TELESYNERGY® will also be installed at Beaumont Hospital in Dublin and TELESYNERGY® Lite will be deployed at Midwestern Regional Hospital in Limerick.