

Alumni study, a follow-up study based on medical examinations conducted at Glasgow University from 1948-1968. This study has contributed to promoting a greater understanding of the role of early life exposures in later chronic cardio-respiratory disease. Dr. McCarron is also prominently involved as a bioinformatics expert in the MONica Risk, Genetics, Archiving, and Monograph (MORGAM) project, as well as the GenomeEUtwin studies.

Dr. Paul Walsh, 2001-2003 Cancer Epidemiology fellow, continued his work at NCRI in 2008, designing and coordinating research and data analysis projects.

CLINICAL TRIALS

Dr. Anne Cody, Chair



A major goal of the Consortium is to strengthen the capacity for cancer centers in Ireland and Northern Ireland to conduct cancer clinical trials, thereby improving patient access to new lifesaving therapies. Since 2001, the Clinical Trials Working Group (CT WG) has worked to support this mission by facilitating funding mechanisms that enable hospitals across the island of Ireland to develop and maintain an effective clinical trials program infrastructure. This endeavor resulted in the establishment of ICORG, which 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. Eleven all-Ireland hospitals form a series of clinical trials hubs for other participating hospitals.

Some key ICORG results from 2008 are summarized below.

ACCRUALS

In 2008, 969 patients were accrued in sixty-eight ICORG studies – a 30% increase over 2007 accruals. Approximately two-thirds of all participating patients were engaged in clinical trials, while the other third participated in translational studies. Breast cancer has remained the central disease area, as 50% of all recruited patients participated in breast cancer studies. However, this percentage is now counterbalanced by additional studies in other disease areas, such as genitourinary, gastrointestinal, and lung cancer. In 2008, new disease-specific clinical trial sub-groups were established in head and neck, melanoma, and skin cancer. These additions will facilitate continued broadening of the ICORG portfolio.

COLLABORATIONS

Collaborative group studies accounted for approximately 40% of all ICORG studies during 2008. The Eastern Cooperative Oncology Group (ECOG) Trial Assigning Individualized Options for Treatment (Rx) or TAILORx study on individualized treatment options in breast cancer was particularly successful and recruited 221 patients in Ireland over the course of the year. Notably, ICORG recruited the group's first American patient for an ICORG-developed trial in the fourth quarter of 2008.

Additionally, collaborations with pharmaceutical companies expanded further in 2008, increasing from sixteen collaborations in 2007 to twenty studies in 2008.

OPERATIONS

Following the recruitment ban instituted in the last quarter of 2007, strict enforcement of staffing limits for hospitals in Ireland had a serious impact on a number of clinical trials sites, as departing staff members could

not be replaced. The HRB engaged with the DoHC and the HSE of Ireland throughout 2008 in order to reach a solution. Towards the end of 2008, staffing problems abated; however, such challenges during the year clearly impacted patient accruals, as some clinical trials sites were unable to commence new trials for a period of time.

Northern Ireland Cancer Clinical Trials Unit

Following the signing of the Consortium MOU, the Northern Ireland Cancer Clinical Trials Unit (NICCTU) was established to coordinate and promote cancer clinical trials throughout Northern Ireland. As part of the Experimental Cancer Medicine Research Division of the CCRCB at QUB, the Unit is one of seventeen Experimental Cancer Medicine Centers (ECMCs) located in the U.K. Each ECMC maintains a portfolio that consists of Cancer Research U.K. (CR-UK), commercial, and local investigator initiated phase I, II, and translational trials.

The NICCTU currently performs three interconnected, yet separate functions, serving as:

- a local cancer Clinical Trials Unit (CTU), developing and coordinating investigator-initiated phase I-III clinical trials and translational studies;
- a vehicle for the development, organization, and clinical delivery of phase I-II trials and translational studies through its role in the Northern Ireland Experimental Cancer Medicine Centre (NIECMC); and
- an evolving regional cancer clinical research network, running phase III-IV cancer clinical trials, as well as other cancer studies in Northern Ireland.

In 2008, the NICCTU recruited 707 cancer patients into forty-seven clinical trials,

with 8.3% of these trials representing incident cancers excluding non-melanoma skin cancer. These figures are based on patient accrual rates for clinical trials open exclusively at the Cancer Centre at Belfast City Hospital. As the Northern Ireland Cancer Trials Network (NICTN) continues to expand, the NICCTU is expected to reach a target goal of 10% patient accrual during 2009. To date, NICTN activities focused primarily on staff induction and training, with a select number of non-complex cancer trials now open for accrual.

In 2008, the NICCTU faced and overcame a number of staffing and hiring challenges. Dedicated clinical research nurses were appointed in the Cancer Units based at Antrim Area Hospital, Craigavon Area Hospital, Ulster Hospital, and at the Royal Belfast Hospital for Sick Children. An additional clinical research nurse will be appointed at Altnagelvin Area Hospital in spring 2009.

Also during 2008, the NICCTU was involved in a number of ECMC network activities, including the ECMC Nurse Network Meeting, the ECMC Bioanalytical and Quality Assurance Meeting, and the Data Management Network Meeting. The NIECMC played a key role in brokering a pioneering collaboration between the pharmaceutical company, AstraZeneca International, the National Cancer Research Institute, and the ECMC network. The NICCTU is currently involved in three out of thirteen novel phase II studies in the NCRI colorectal and lung portfolios.

In addition, the NICCTU continued to promote all-Ireland clinical trials collaboration with U.K. and U.S. counterparts, through its partnership with ICORG. In 2008, the NICCTU's relationship with ICORG facilitated increased involvement in ECOG studies, as the NICCTU was

selected as an ECOG registered clinical trials site. The first ECOG clinical trial will open in Belfast, in early 2009.

INFORMATION TECHNOLOGY

Professor Donal Hollywood, Chair

Each year, the Information Technology Working Group (IT WG) works to expand existent technological capabilities and build new information sharing infrastructures that enhance communication between medical and scientific communities on the island of Ireland. The IT WG also works to facilitate training and education programs, support the coordination of clinical trials, ensure effective data management, and strengthen health care delivery systems across the island of Ireland.

TELESYNERGY®

The IT WG focused its efforts during 2008 on further deploying the TELESYNERGY® system within the National Cancer Control Network in Ireland. The TELESYNERGY® system, a multimedia medical imaging and conferencing system developed by the NIH's Center for Information Technology (CIT), enhances collaboration among Consortium partners on a variety of projects and activities across the island of Ireland and throughout the U.S.



TELESYNERGY® installation in
Beaumont Hospital, Dublin.

In August 2008, the TELESYNERGY® system was successfully implemented at Beaumont Hospital in Dublin. Beaumont Hospital was recently identified by the HSE as one of eight core cancer centers that will form the nexus of future cancer treatment services within the rapidly developing NCCP. In addition, Beaumont Hospital will be one of four major sites comprising the forthcoming National Network and Programme for Radiation Oncology. For further information on TELESYNERGY® use at Beaumont Hospital, please visit <http://telesynergy.nih.gov/beaumont.html>.

Currently, the TELESYNERGY® system is operational in all major NCCP hospitals in Ireland. The NCCP initiated a review in late 2008 to identify remaining hospital sites that may benefit from TELESYNERGY®. It is expected that review of the entire network will be completed in 2009.

The TELESYNERGY® system facilitated an increasing range of activities and services in 2008, including:

- Inter-hospital telemedicine meetings, including most tumor board and oncology multidisciplinary meetings.
- Joint educational activities with Princess Margaret Hospital in Toronto, Canada.
- All committee meetings of the Irish Institute of Radiography.

Additionally, the TELESYNERGY® network continued to facilitate the development and extension of education and training programs in 2008. The Faculty of Radiologists in Ireland, in conjunction with the Royal College of Surgeons in Ireland, offers a diverse variety of post-graduate training programs in the field of radiology and other areas, including radiation protection and alternative methods of imaging. The TELESYNERGY®