

IRELAND'S OFFICIAL PHARMACY PUBLICATION

IPU *Review*

DECEMBER 2018 /
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Pictured at the launch of the *Just Ask!* public information campaign (L to R) Emily Hourican, journalist, cancer survivor and guest speaker at the launch and Evelyn O'Rourke, Member of the Board of Cancer Trials Ireland and RTÉ broadcaster.

Cancer trials can offer more treatment options

Despite the increasing numbers of cancers being successfully managed, cancer is still the second leading cause of death. It is estimated that one in six deaths is due to cancer, with an estimated 9.6 million deaths in 2018 globally.

Incidences of cancer in Ireland reflect what is happening globally. The number of new cases of invasive cancer cases (including non-melanoma skin cancer), is expected to increase by between 86% and 125% for females and by between 126% and 133% for males, between 2010 and 2040.

In Ireland, the Department of Health's 2015 – 2017 *Statement of Strategy* notes that the incidences of cancer are projected to double by 2040.

While cancer is a global issue, for the past 20 years Irish oncologists and research teams have been searching for the answers to cancer through cancer trials.

Location of hospital-based Cancer Trials Research Units

- Letterkenny University Hospital
- Sligo University Hospital
- University Hospital Galway
- University Hospital Limerick
- Cork University Hospital
- Bon Secours Hospital, Cork
- Midland Regional Hospital—Tullamore
- University Hospital Waterford
- Beaumont Hospital
- Mater Misericordiae University Hospital
- St James's Hospital
- Tallaght University Hospital
- St Luke's Radiation Oncology Network
- St Vincent's University Hospital
- Beacon Hospital
- Our Lady's Children's Hospital Crumlin

Gateway

Every cancer drug has, at one stage, had to prove its efficacy and safety through a cancer trial. They are the gateway to better treatments.

Since Cancer Trials Ireland was established in 1996, more than 15,000 patients have participated in over 350 cancer trials.

Cancer trials can benefit patients in two ways; they help find better treatments and they can provide access to promising, and potentially life-enhancing treatments that are not yet available through the mainstream health service. This can give trial patients potentially more treatment options.

At any one time, there are in the region of 6,000 patients on a cancer trial in Ireland. Participation is open to all who are suitable and there is no charge.

Approximately 100 cancer trials are recruiting patients

in 16 hospitals around the country (see panel left).

A further 50 trials are in the data collection and analysis stage.

International collaboration

Most cancer trials in Ireland fall into two categories.

There are in-house trials, which are developed and run by oncologists and their research teams in one of the 16 cancer trials research units around the country, usually underpinned by their ongoing research programmes.

Collaborative trials involve Cancer Trials Ireland research teams opening trials in Ireland, which are part of larger international trials, initiated by some of the leading research groups around the world.

Trials are also opened and run in Ireland by pharmaceutical companies.

Cancer Trials Ireland's ongoing *Just Ask!* public information campaign (supported by MSD, Pfizer, AbbVie, Novartis and Roche) is designed to ask healthcare professionals, including pharmacists, to encourage their patients to *Just Ask!* their oncologists if there is a cancer trial open in Ireland that may be suitable for them.

A list of all cancer trials open in Ireland is available at www.cancertrials.ie.

Cancer Trials Ireland is a not-for-profit registered charity, partly funded by the Irish Cancer Society and the Health Research Board (HRB).

Cancer trials investigate new uses for common drugs

The design of cancer trials can vary. For example, they can investigate tissue samples, diagnostics methodologies, new combinations of existing

Announcing the opening of the Add-Aspirin trial (L to R) Prof Bryan Hennessy, Clinical Lead, Cancer Trials Ireland; Emma Corcoran, patient advocate; Dr Janice Walshe, Consultant Medical Oncologist at St Vincent's University Hospital, Dublin; and Dr Greg Leonard, Chief Investigator for the Add-Aspirin trial in Ireland, Consultant Medical Oncologist, Galway University Hospital.





drugs, new approaches to radiotherapy and new novel drugs. But, they can also investigate the potential for repurposing existing commonly available drugs.

A Phase III trial, recently opened in Ireland called Add Aspirin, is investigating if aspirin, the inexpensive commonly available drug, can prevent early stage cancer returning after treatment.

Another earlier stage (Phase 1b) trial, due to open shortly, will assess if the mood stabilising agent lithium, can help to slow or stop cancer.

The Add Aspirin trial is the first ever large-scale trial to investigate whether taking aspirin daily for five years after treatment, can prevent a patient's cancer returning, and ultimately prolong life. The trial involves collaboration among experts from Ireland, UK and India. It will have 11,000 participants from all three countries.

The trial will recruit over 300 eligible volunteers in Ireland, from 10 participating hospitals who have had, or have started, treatment for early stage cancer of the breast, stomach, oesophagus (food pipe) or prostate.

To date, studies have looked primarily at the effect of aspirin on heart disease and its side-effects, and found that fewer people taking aspirin appeared to develop cancer. Among those who developed cancer, the cancer appeared to be less likely to spread.

In Ireland, the trial is co-ordinated by Cancer Trials

Ireland and supported by funding from the Health Research Board and the Irish Cancer Society. Bayer is providing the aspirin that will be used during the trial.

Dr Gregory Leonard, Consultant Medical Oncologist, Galway University Hospital, is the trial's Chief Investigator for Ireland. The overall Chief Investigator for the study is Professor Ruth Langlely, based at UCL in London.

Dr Leonard said that while aspirin has been in use for over 100 years for pain relief, and more recently to prevent heart attacks and strokes, there has been a growing body of evidence during the past decade of its potential as an anti-cancer agent. "This is the first trial ever to investigate if aspirin could stop or prevent the return of cancer among such a significantly large group of patients with early stage cancer. At a time when we are used to new cancer treatments being relatively costly, the possibility of repurposing an inexpensive, generic drug that is available worldwide, to stop or slow cancer, is potentially ground-breaking. The results of this trial could have a huge impact on the global cancer burden, particularly given the



Together, we're finding answers to cancer.

increasing cancer incidence in lower resource countries," he said.

Those interested in taking part in the Add Aspirin trial should talk to their

oncologist, who will be able to consider whether they are suitable for the trial.

Irish women participate in international trial to reduce need for chemotherapy

As well as testing new promising treatments, cancer trials can investigate new ways to establish the effectiveness of existing treatment options.

The TAILORx trial is one of the first large-scale trials to examine a methodology for personalising post-operative breast cancer treatment.

Results of this ground-breaking cancer trial, in which 690 women from Ireland participated, published earlier this year, show that chemotherapy can be avoided for 70% of women with the most common type of early stage breast cancer (HR-positive, HER2-negative, node-negative breast cancer). The findings suggest that chemotherapy may be considered for the remaining

30% of women. The TAILORx trial involved 10,273 women with early-stage breast cancer, across 1,182 research units in Ireland, United States, Australia, Canada, New Zealand and Peru. The Irish arm of the trial was conducted by Cancer Trials Ireland and led by Professor Maccon Keane, Consultant Medical Oncologist, University Hospital Galway, as the Chief Investigator.

Reflecting Ireland's strong support for cancer trials, St Vincent's University Hospital in Dublin had the second highest number of participating patients from the 1,182 research units involved in the trial.

Professor Keane said that the TAILORx trial result is a major advance in precision medicine for women with hormone receptor positive node negative breast cancer. "It confirms that, using the 21-gene expression test on tumours, we can identify which women will benefit from endocrine (hormone) therapy only, thus eliminating the need for them to have chemotherapy. It also helps identify those women with this disease who really do benefit from the chemotherapy they receive. Having the trial in Ireland has enabled more personalised treatment recommendations for women with this stage and type of breast cancer, as we have had access to the test through the HSE since 2011," he said.