

Pre-Budget 2017 Submission

*For every €1 the
Exchequer invests in
cancer trials it will save
more than €2 in cancer
treatment costs.*

*Investment by the
Exchequer in Ireland's
cancer trials
infrastructure makes
economic sense.*



*Together, we're finding
answers to cancer.*

Introduction

Cancer Trials Ireland has a 20 year history of successfully ensuring that the Exchequer's investment in cancer trials has consistently delivered multiples of this investment.

For example, as a result of the €3 million invested by the Exchequer in 2016, Cancer Trials Ireland is expected to generate an additional €4.5 million in income from other sources, save the HSE at least €6.5 million in cancer drugs cost, generate almost €6 million in tax revenues, contribute €16.5 million to Ireland's GDP and support over 230 jobs, mostly high quality specialist positions.¹

To maintain this record and adapt to the changing environment it has recently strengthened its capabilities at Board, clinical and management level and embarked on a new strategic direction.

It is now in a very strong position to leverage further the Exchequer's investment in cancer trials by attracting extra investment from global pharmaceutical companies and international funders.

The recommendations in this submission will help Cancer Trials Ireland secure this additional investment and open more cancer trials in Ireland.

These trials will provide more patients with access to drugs that would not otherwise be available to them and more concentrated care. They will save the health service millions of euro in cancer drugs costs. They will also enhance further Ireland's position internationally as a location of excellence in cancer trials.

Cancer Trials Ireland is funded by a combination of grants (mainly from the Health Research Board and the Irish Cancer Society) and other income (mainly pharmaceutical industry funding).

Cancer Trials Ireland's Group Central Office (GCO) activity level has grown very significantly over the last decade (revenues more than trebling), and the bulk of this growth has been financed by sources other than grants. In 2006 grants represented 64% of total income, while for 2016 they are projected to represent 42%.

In addition, Cancer Trials Ireland disburses HRB and pharmaceutical industry funding for clinical trials in hospitals around the country. These are projected to amount to €2.4 million and €1.8 million respectively in 2016.

Additional investment by the Exchequer in Ireland's cancer trials infrastructure makes economic sense.

¹ Health and Economic Impacts of Cancer Trials in Ireland, DKM Economic Consultants (2016).
(<http://www.cancertrials.ie/news-events/health-economic-impact-report-of-cancer-trials-in-ireland>)
Much of the data referred to in this document is drawn from this report.

This submission is presented in four parts.

- 1: Summary of recommendations.
- 2: Why cancer trials are necessary.
- 3: How Cancer Trials Ireland multiplies the Exchequer's investment.
- 4: Cancer Trials Ireland's recommendations.

Cancer Trials Ireland
Charity No. CHY12492
60 Fitzwilliam Square Dublin 2, Ireland
Tel: +353 (0)1 6677211
info@cancertrials.ie
www.cancertrials.ie

1. Summary of recommendations.

Summary of the recommended investments the Exchequer should make in developing Ireland's cancer trials infrastructure in Budget 2017.

1. *Provide funding for the development of a highly secure cloud based integrated trial data management system to enable a dashboard based compliance, variance and performance reporting system: Recommended funding: €800,000 - €850,000 to be invested over three years.*
2. *Establish a fund to support HSE employed Oncologists (through locum and other resources) to source, initiate, lead and complete cancer trials in Ireland. Recommended funding: €1 million recurring.*
3. *Provide the HSE with ring-fenced funding for clinical research resource in the 14 cancer trials² research units – staff and capital. Recommended total funding: €1.4 million (€700,000 once off and €700,000 recurring).*
4. *Provide direction to the HSE to ensure that uniform pharmacy fees are applied across all hospitals that host cancer trials. Estimate cost: Minimal.*

Implementation of these recommendations will enable Cancer Trials Ireland and other clinical research organisation to extend the impact of the Exchequer's investment in cancer and clinical trials for the economy and for patients with cancer.

2. Why cancer trials are necessary

The number of new cases of cancer diagnosed each year in Ireland is 20,454³. The number of people who die each year of cancer is 9,056. This is just slightly below the numbers who die of cardiovascular disease, which is currently the biggest cause of death in Ireland⁴.

While significant progress has been made in the fight against cancer, the Department of Health's 2015-2017 Statement of Strategy predicts that the incidences of cancer in Ireland are projected to double by 2040.

These trends highlight that the current methods of preventing, diagnosing and treating cancer are inadequate. They also highlight that to reverse this trend new and more effective prevention, diagnostic and treatment modalities will be needed.

To identify and prove these new modalities requires rigorous local, national and global cancer trials. Without them, the swelling tide of cancer will not be arrested.

² Cork University Hospital, Bon Secours, Cork, University Hospital Limerick, Midland Regional Hospital, Tullamore, University Hospital Galway, Sligo General Hospital, Letterkenny General Hospital, Waterford Regional Hospital, St Vincents University Hospital, Beaumont Hospital, St James' University Hospital, Tallaght Hospital, Mater Misericordiae University Hospital and St Luke's Hospital.

³ National Cancer Registry Ireland.

⁴ CSO

This is why the work of Cancer Trials Ireland and the associated research teams and their leadership around the country is critically important for so many people.

3. How Cancer Trials Ireland multiplies the Exchequer's investment

Cancer Trials Ireland was set up in 1996 to open more cancer trials and make Ireland a more attractive location for trials. It leverages the Exchequer's investment and other grants in four ways.

- i. Cancer Trials Ireland leverages the investment it receives from the Exchequer many times over by attracting inward investment from global pharmaceutical companies and international funders.*

In 2016 Cancer Trials Ireland will receive from the Exchequer just over €3 million. It will leverage this investment and generate a further €4.5 million from other sources such as the pharmaceutical industry, international funders and granting agencies. As a direct result of its work it will add a total of €16.5 million to Irish GDP per annum, and generate tax revenues for the Exchequer of €5.8 million per annum. Almost 200 people will be employed working on cancer trials in Ireland. Taking into account supply chain and other multipliers, this number rises to over 230.

Participating hospital-based cancer trials research units have confirmed that the grants they receive enable them to secure funding from non-Exchequer sources. One found that for every €1 in grant funding they received, they generated a further €3 in income from industry for trials.

- ii. As cancer trials provide participants with free access to treatments they save the HSE millions of euro on drugs costs which they would otherwise have to provide if the trials were not opened.*

Working with almost all cancer treating specialists in Ireland through 14 hospital based research units, more than 350 Cancer Trials Ireland cancer trials have been opened involving 15,000 patients since 1996.

Conservatively, Cancer Trials Ireland saves the HSE in the region of €6.5 million annually in cancer drugs costs directly from its cancer trial activity. This excludes the costs of experimental drugs, avoided treatment costs (as in the case of the Oncotype DX test⁵), and the benefits of improved health and longer lives for patients, leading to lower future healthcare costs.

By this metric alone for every €1 the Exchequer invests in cancer trials it will save more than €2 in cancer drug costs. If the costs associated with monitoring and tests and

⁵ Oncotype DX is a test which can help doctors decide if a patient would benefit from chemotherapy as part of their treatment.

contributions to staff are added in, the impact would be greater. By applying the findings of a UK study⁶ to the number of people on an open trail during 2015, the savings to the HSE would be calculated at €10.7 million in that year alone.

iii. Cancer Trials Ireland trials have added many quality-adjusted life years to participants which have delivered measurable economic benefits.

Based on a small sample of case studies of trials (TAILORx, Monotherapy in Untreated Melanoma, BCIRG 006, PALOMA-1), it is estimated that the health benefits of each trial (considering only the Irish patients who participated in the trials, for the period of follow-up), ranges from 6 to 16 added quality-adjusted life years (QALYs) per trial. The related economic benefits range from €0.28 to €0.72 million per trial. Subsequent benefits, when therapies become available to the generality of patients, would be a multiple of these values.

iv. Cancer Trials Ireland is contributing to bringing to market new diagnostics and treatments that will extend and enhance lives and reduce treatment costs.

When Irish cancer centres and patients participate in a successful trial, the treatment in question has a local familiarity and a readymade advocacy during the approval process. This means that the benefits of the diagnostic or treatment for patients and the economy can be made available more rapidly than in countries where trials are not available.

A specific example of this type of tangible benefit is the TAILORx Trial. One hundred and ten patients on this trail avoided three months of chemotherapy and approximately three months recovery from the effects of chemotherapy. The HSE saved approximately of €766,000 (ex VAT) because it did not have to provide these patients with chemotherapy and the trial generated €0.5 million in added quality-adjusted life years for participants.

Ireland's strong involvement in this trial resulted in it being the first in Europe to introduce the test, OncotypeDX, that was the subject of the Trial. Its early introduction generated a considerable return for patients and the health service. It is estimated that every year it generates an economic benefit of €1.06 million and treatment costs saving to the HSE of €0.56 million in chemotherapy costs.

⁶ Liniker, E., et al., 2013, "Treatment costs associated with interventional cancer clinical trials conducted at a single UK institution over 2 years (2009–2010)", in *British Journal of Cancer* (2013) 109, 2051–2057, <http://www.ncbi.nlm.nih.gov/pubmed/24064969>.

5. Cancer Trials Ireland’s recommendations.

The benefits outlined above could not be achieved without the existence of the cancer trials professionals and infrastructure which has been generated over the past 20 years with the considerable support from the Exchequer.

To build on this track record, continue to deliver the tangible benefits outline above and further develop Ireland as an attractive location of cancer trial we recommend the following be included in the Budget 2017.

The Department of Health’s Statement of Strategy 2015 – 2017 provides a helpful context to these recommendations:

“With cancer incidence projected to double by 2040, the growth in demand for cancer services will continue to increase, particularly in view of an ageing population. A key task in the coming years will be to work to prevent cancer occurring in the first place as far as possible and to tackle cancer early when it does occur.”

1. *Provide funding for the development of a cloud based integrated trial data management system to enable a dashboard based compliance, variance and performance reporting system: Recommended once off funding: €800,000 - €850,000 to be spent over three years.*

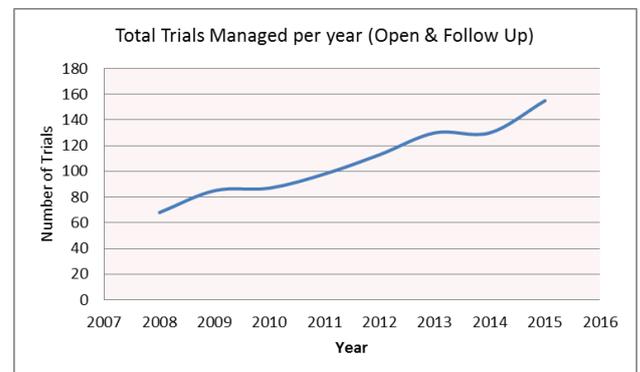
Cancer Trials Ireland has grown rapidly in recent years. The number of trials (open and in follow up) has been increasing.

To manage an increasing volume of high quality and relevant cancer trials it is essential that Cancer Trials Ireland operates within and leads best practice in cancer trials

while maximising the resources available. At the same time it must compete against stiff competitions from cancer trials organisations in other countries.

To do this Cancer Trials Ireland needs to streamline its recording and monitoring systems by developing an integrated trial data management system that is capable of monitoring and reporting on all aspects of all trials in an integrated way.

Currently each trial in Cancer Trials Ireland’s portfolio is managed as a separate project within separate disease areas. While there is a consistency in approach across the trials in relation to processes, procedures and protocols, managing each trial as a separate project is labour intensive and, critically, makes it difficult to compare and benchmark each trial’s performance at an operational level.



In addition, the absence of integrated oversight mechanisms to flag possible variances, delays and other issues that require timely intervention at clinical, operational and financial levels means that oversight can be resource intensive. It is necessary for Cancer Trials Ireland to upgrade its current trial data management system and develop a more integrated system which provides performance measurement and management oversight across the entire portfolio.

Having an integrated system will also assist in comparing budgets and costs between trials and make establishing the root cause of budgetary variances, where they arise, transparent. This will provide valuable learning for future projects and enhance the organisation's proposition when seeking to attract new global trials to Ireland.

- 2. Establish a fund to support HSE employed Oncologists (through locum and other resources) to source, initiate, lead and complete cancer trials in Ireland. Recommended funding: €1 million recurring.*

Oncologists and their research teams are the main driving forces behind the opening of trials, the recruitment of patients and the analysis of results. Due to the nature of the work it can be demanding on their time beyond their core clinical practice. While in general the research teams are paid for their work on cancer trials, the work oncologists do on cancer trials is in addition to their normal contracted duties. Coupled with this, there is the strong evidence which shows that when oncologists have access to protected time they source and open more cancer trials in their areas of specialisation. However, the difficulties associated with putting in place part time and short term locums to create protected time for Oncologists working on cancer trials in the current climate is problematic and can be disruptive for the wider health services.

To support the research of Oncologists and encourage more Oncologists to source and undertake research we recommend that a fund of €1 million euro is made available for oncologists to apply to, to put in place the resources such as clinical researchers to support their individual cancer trials work. This fund could be administered by the National Cancer Control Programme or the Health Research Board.

We recommend that that this fund is made available on a recurring basis

- 3. Provide the HSE with ring-fenced funding for clinical research resource in the 14 cancer trials research units – staff and capital. Recommended total funding: €1.4 million (€700,000 once off and €700,000 recurring).*

Despite the positive multiplier effect of Cancer Trials Ireland's work, the level of grant funding per patient participating on a cancer trials in Ireland has fallen by 45% over the last decade, from a peak of €3,650 in 2009 to €2,020 in 2015. It will experience a further 20% reduction in 2016.

While the organisation is seeking to open more trials on behalf of pharmaceutical companies and international funders to offset this decline, it is essential that it has in

place the infrastructure (staff and facilities) to display its competency to compete for this work, and subsequently meet the demands generated from securing new work.

In addition, it is important to note that Cancer Trials Ireland was set up primarily to enable clinical investigators develop trials based on clinical observations and experiences which serve the long term public interest. Critically these public interest trials rely on support from research units and Exchequer grants. For example, Cancer Trials Ireland's largest "home-grown" study is investigating two standard of care treatments in cancer of the oesophagus. Another trial driven by the public interest is the BIG 8-13 - POSITIVE trial.⁷

There are many equally important questions which investigators are bringing forward which require support. Without access to a functioning cancer trials infrastructure (staff and facilities) commercially driven and important, but commercially unattractive cancer trials, could not be pursued.

Given the opportunities to attract funding from outside Ireland, the huge savings Cancer Trials Ireland can generate for the health service in drugs cost and the many lifesaving and enhancing benefits it can deliver, it is seeking funding to bolster the existing network of cancer trials research units in the 14 hospitals around the country.

It is seeking a recurring allocation of €700,000 towards staff costs to overcome the situation where they are relatively transient as they rely on trial funding available alone and have no recurring support from their host hospital. Staff turnover can result in the loss of highly valuable expertise.

We are also seeking a once off allocation of €700,000 to upgrade the research facilities in the 14 research units which in some instances consist of porta cabin sheds. This funding would be allocated on a business case basis.

4. Provide direction to the HSE to ensure that uniform pharmacy fees are applied across all hospitals that host cancer trials. Estimate cost: Minimal.

During cancer trials different hospitals charge different pharmacy fees sometimes for the same service. This practice creates disquiet among pharmaceutical companies and international collaborative groups.

We would appreciate if the Department of Finance through the Department of Health could provide guidance in this area and support the implementation of a uniform pharmacy fee schedule across the hospital network for cancer trials.

Ends

⁷ A study evaluating the pregnancy outcomes and safety of interrupting endocrine therapy for young women with endocrine responsive breast cancer who desire pregnancy (POSITIVE). SPONSOR International Breast Cancer Study Group (IBCSG)