

Cancer Trials Ireland CLG

Directors' Report and Financial Statements  
for the financial year ended  
31 December 2019

Registered Number: 268044

**CANCER TRIALS IRELAND CLG**

**DIRECTORS' REPORT AND FINANCIAL STATEMENTS  
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2019**

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**CANCER TRIALS IRELAND CLG**

**DIRECTORS AND OTHER INFORMATION**

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**DIRECTORS**

Dr. Jonathan Westrup (Chairman)  
Darren Byrne  
Dr. Linda Coate (Resigned 24<sup>th</sup> January 2019)  
Dr. Jerome Coffey  
Dr. Leisha Daly  
Berchmans Gannon  
Diane Hanly  
Prof. Bryan Hennessy  
Dr Paul Kelly (Resigned 15<sup>th</sup> March 2019)  
Prof. Ray McDermott  
Dr. Robert O'Connor  
Evelyn O'Rourke  
Prof John Crown (Appointed 7<sup>th</sup> November 2019)

**COMPANY SECRETARY**

Mr. Robert Cosgrave

**REGISTERED OFFICE  
AND BUSINESS ADDRESS**

Innovation House  
Old Finglas Road  
Glasnevin  
Dublin 11  
D11 KXN4

**COMPANY NUMBER**

268044

**CHY NUMBER**

12492

**CRA NUMBER**

20036676

**INDEPENDENT AUDITORS**

Deloitte Ireland LLP  
Chartered Accountants and Statutory Audit Firm  
Deloitte & Touche House  
Earlsfort Terrace  
Dublin 2

**SOLICITORS**

Eversheds Solicitors  
One Earlsfort Centre  
Earlsfort Terrace  
Dublin 2

**BANKERS**

AIB Bank plc  
Unit 33 Blackthorn Road  
Sandyford  
Dublin 18

Permanent TSB  
2/4 Upper Baggot Street  
Dublin 4

## CANCER TRIALS IRELAND CLG

### DIRECTORS' REPORT FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2019

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The Directors present their annual report, together with the audited financial statements, for the financial year ended 31 December 2019.

#### PRINCIPAL ACTIVITY AND REVIEW OF THE ORGANISATION

Almost all cancer treating specialists in Ireland are members of Cancer Trials Ireland.

The organisation's trials are carried out in 14 hospital-based Cancer Trials Units (CTUs) across the country, supported by a central team of clinical researchers, project managers, data managers and other experts. As well as managing its own in-house academic trials, Cancer Trials Ireland also works with global pharmaceutical companies and international collaborative research groups, which generates substantial inward investment and access to innovative treatments for cancer patients.

Cancer is a global health issue.

The World Health Organisation reports that cancer is the second leading cause of death globally and is responsible for an estimated 9.6 million deaths in 2018. Globally, about 1 in 6 deaths is due to cancer.

According to the 2019 Annual Report from the National Cancer Registry of Ireland (NCRI), cancer is the most common cause of death in Ireland, accounting for almost 31% of deaths in 2016. The approximate annual average of deaths from invasive cancer occurred from 2014-2016 and was 9,020. It is estimated that about 35,440 invasive cancers were diagnosed annually in 2017, 2018 and 2019 in Ireland.

Taking the ageing population into account, NCRI projections (2019) show cancer rates have stabilised or even declined in recent years. Nevertheless, projected population growth and ageing in Ireland will result in a substantial increase in the number of cancer cases in the coming decades, potentially doubling from current levels by 2045<sup>1</sup>.

Meanwhile, the Department of Health's 2015-2017 Statement of Strategy notes that the incidences of cancer are projected to double by 2040. It states that *"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"*.

Reflecting this commitment, the key elements of the 3<sup>rd</sup> National Cancer Strategy, developed in 2016, include the KPI to double the number of patients on drug trials from 3% to 6% by 2020.

Cancer Trials Ireland had a decrease in numbers of patients on drug trials in 2019, substantially more resource are needed to reach the 6% KPI. Future support from the Health Research Board, Irish Cancer Society and philanthropy will continue to enable Cancer Trials Ireland to increase those numbers in future years, but significant government investment in cancer trials infrastructure is needed

#### OBSERVATIONS AND ACTIVITIES

All the trials were worked on by staff at Cancer Trials Ireland General Central Office.

In 2019, approximately 26% of the open trials are in-house academic trials (2018: 20%) funded by the grants received from the Health Research Board and the Irish Cancer Society. 45% (2018: 41%) of these open trials involved collaboration with cancer research groups and/or are Investigator Initiated Studies which are funded through pharmaceutical companies. The 29% balance of open trials are run by international pharmaceutical companies in Irish hospitals where staff at the General Central Office do limited work and receive little or no support. However, to capture a complete picture of cancer clinical trials in Ireland, we adopt these trials into our portfolio.

In 2019 accruals on Cancer Trials Ireland studies was split between 320 patients (379 in 2018) on Investigational Medicinal Product (IMP) studies and 699 (661 in 2018) on non-IMP studies.

The work of Cancer Trials Ireland, and the associated research teams and their leadership around the country is critically important for people with cancer. Following an organisational review completed in 2014, Cancer Trials Ireland embarked on an important strategic change programme to enable it to move from operating as a small organisation to a medium-sized clinical trials group.

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<sup>1</sup> [https://www.ncri.ie/sites/ncri/files/pubs/CancerIncidenceProjections\\_NCRI\\_fullreport\\_09042019\\_final.pdf](https://www.ncri.ie/sites/ncri/files/pubs/CancerIncidenceProjections_NCRI_fullreport_09042019_final.pdf)

## CANCER TRIALS IRELAND CLG

### DIRECTORS' REPORT (CONTINUED) FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2019

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#### VISION AND MISSION

Cancer Trials Ireland's mission is to develop and provide access to the most efficient and effective network which includes research units, clinical and operational leadership, and enabling services. Our vision is focused on one primary purpose: To provide every patient with cancer access to high-quality and potentially life altering cancer trials and make Ireland a highly attractive location to open cancer trials. Central to Cancer Trials Ireland's strategy to achieve this is to continue to develop its unique hub (head office) and spoke (cancer trials research units) network.

The 5 strategic pillars are the key to enable Cancer Trials Ireland to achieve this vision and mission:

1. Governance
2. Profile
3. Funding Model
4. Operational Capabilities
5. Clinical Capabilities

#### STRUCTURE, GOVERNANCE AND MANAGEMENT

The Board rotates at the AGM every year as per the Constitution. The Board is chaired by Dr. Jonathan Westrup, appointed in 2014 and he is a strategy and governance expert. The Board meets 5 times per year and permanent agenda items include reports from Clinical Executive Committee and Audit Committee, Governance, Strategy, Conflict of Interest Declarations and Finance. In 2019, the Board met 5 times. (2018: 5)

The members of the Board are qualified to hold their position and represent a range of skills; governance, patient advocate, clinical oncologists, radiation oncologists, industry representative, finance and National Cancer and Control Programme (NCCP) representative. In 2018 the Board appointed a new subgroup called the Patient Consultant's Committee (PCC) set up to integrate the patient voice and experience in the governance structure of the organization.

The Clinical Executive Committee (CEC), Scientific Management Group and Disease Specific Sub-Groups monitor progress on the ongoing clinical trials, make decisions on the adoption of new trials to the portfolio and the CEC reports to the Board of Directors through its Chair; Prof. Bryan Hennessy, Clinical Lead.

The Audit Committee is a subcommittee of the Board and was established in the summer of 2016 and met 4 times in 2019 (2018: 3) Darren Byrne is the chair of the Audit Committee and member of the Board of Directors.

#### OUR BOARD OF DIRECTORS

A number of directors are Clinical Leads, Principal Investigators or involved in collaborative studies with the company ("Cancer Trials Ireland"). All trials and research studies were approved in the normal course of business. The directors have no financial beneficial interest in the research, nor did they receive remuneration for their contribution to this research. Details of the directors and their contribution to the company are outlined below:

##### **Dr. Jonathan Westrup, Chair**

Dr. Jonathan Westrup is a partner of Acorn Governance Solutions and a company director.

##### **Berchmans Gannon**

Legal Expert, formerly Beauchamps Solicitors.

**OUR BOARD OF DIRECTORS (CONTINUED)**

**Prof. Bryan Hennessy, Clinical Lead**

Consultant Medical Oncologist in Beaumont Hospital, Dublin, and Our Lady of Lourdes Hospital, Drogheda, Lecturer at Royal College of Surgeons in Ireland (RCSI), an Adjunct Professor in the Division of Cancer Medicine at MD Anderson Cancer Centre (MDACC). Cancer Trials Ireland protects Prof. Hennessy's time through funding the RCSI where his research work is carried out, this funding is used to resource the department to employ a researcher so that Prof. Hennessy can carry out his duties as Cancer Trials Ireland Clinical Lead.

**Darren Byrne, Chair of Audit Committee**

Commercial Experienced Chartered Accountant / CFO and Non-Executive Director.

**Evelyn O'Rourke, Patient Advocate**

Radio and Television Broadcaster with RTÉ.

**Dr. Jerome Coffey**

Director of the National Cancer Control Programme (NCCP). The NCCP are tasked with the responsibility of implementing the next Cancer Strategy where there are key performance indicators for clinical trials.

**Dr. Leisha Daly**

Dr Leisha Daly is Senior Director Government Affairs, Supply Chain EMEA & J&J Ireland at Johnson & Johnson since September 2018. She was previously Country Director of Janssen and was a director of the Irish Pharmaceutical Healthcare Association up to September 2018. She has been a director of Janssen Sciences Ireland (Unlimited) Company since April 2017. Dr Daly is not a member of the Board of Directors of Janssen who are involved in some collaborative studies with Cancer Trials Ireland Investigators.

**Dr. Linda Coate**

Consultant Medical Oncologist, University Hospital Limerick.

**Diane Hanly**

Chair of the Patient Consultant's Committee.

**Dr. Paul Kelly**

Consultant Radiation Oncologist at Cork University Hospital. Dr. Kelly is an investigator on a number of trials in the Cancer Trials Ireland portfolio.

**Prof. Ray McDermott**

Consultant Medical Oncologist at the Adelaide Meath & National Children's Hospital, Tallaght, and St Vincent's University Hospital, Dublin. Prof. McDermott is an investigator on a number of trials in the Cancer Trials Ireland portfolio.

**Dr. Robert O'Connor**

Head of Research at the Irish Cancer Society. The Irish Cancer Society award a grant to Cancer Trials Ireland every year. Dr. O'Connor is not a member the Board of the Irish Cancer Society.

**Prof. John Crown**

Consultant Medical Oncologist at St Vincent's Hospital. Prof. Crown is an investigator on a number of trials in the Cancer Trials Ireland portfolio.

## **CANCER TRIALS IRELAND CLG**

### **DIRECTORS' REPORT (CONTINUED) FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2019**

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#### **OUR BOARD OF DIRECTORS (CONTINUED)**

##### **DIRECTORS AND SECRETARY**

The directors and secretary who served throughout the year, except as noted, were as follows:

##### **Directors:**

Dr. Jonathan Westrup (Chairman)  
Darren Byrne  
Dr. Linda Coate (Resigned 24<sup>th</sup> January 2019)  
Dr. Jerome Coffey  
Dr. Leisha Daly  
Berchmans Gannon  
Diane Hanly  
Prof. Bryan Hennessy  
Dr. Paul Kelly (Resigned 15<sup>th</sup> March 2019)  
Prof. Ray McDermott  
Dr. Robert O'Connor  
Evelyn O'Rourke  
Prof. John Crown (Appointed 7<sup>th</sup> November 2019)

##### **Secretary:**

Mr. Robert Cosgrave

In accordance with the Constitution, the longest serving directors must retire each year but may offer themselves for re-election.

#### **ACHIEVEMENTS AND PERFORMANCE**

- In 2019, Cancer Trials Ireland facilitated a HRB-appointed International Review Committee (IRC) to review the scientific performance of Cancer Trials Ireland and to make recommendations that could validate/inform the design of a new funding model. In parallel, BDO were commissioned by the HRB to conduct a review of Cancer Trials Ireland governance, management and financial processes to enable the HRB team to plan for the future cancer trials call. As a result, the HRB committed to an extension of the current grant cycle (2016 - 2018) to the end of 2021 and will fund a new grant call from January 2022 for 5 years.
- Cancer Trials Ireland ran the 4<sup>th</sup> successful externally funded Just Ask Your Doctor public information campaign communicating with the public and members on radio and media interviews on the value of cancer trials.
- Cancer Trials Ireland advocacy activities in 2019 included making representations to the Department of Health, NCCP and the Minister for Health's office;
- In 2019, for the second year running, a group of volunteers came together to offer their support to Cancer Trials Ireland and held a lunch to raise awareness and funds to help Cancer Trials Ireland's important work. Some of the volunteers are related to Directors of the company and others are people with an interest in our mission to do more clinical trials for people with cancer. Patients who took part in some of our trials were represented by friends and family and were the biggest supporters at the event. The success of the event is an incredible testament to the work of the team at Cancer Trials Ireland.
- Cancer Trials Ireland facilitated regular Stakeholder Engagement and Patient Advocate Advisory Group (PAAG) meetings in 2019
- Pat Smullen and Horseracing Ireland approached Cancer Trials Ireland in the summer of 2019 to help raise funding for Cancer Trials Ireland and, in particular, pancreatic cancer trials. The horseracing community came together at the Longines Champions Weekend event in September 2019. The public and friends of Horse Racing Ireland attending the events over the weekend raised over €2.5million.
- The increased revenue raised has enabled the organisation to build capacity and establish new trial options in pancreatic cancer

## **CANCER TRIALS IRELAND CLG**

### **DIRECTORS' REPORT (CONTINUED) FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2019**

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#### **FINANCIAL REVIEW**

Cancer Trials Ireland is funded by grants from the Health Research Board, the Irish Cancer Society and St Luke's Institute of Cancer Research. The organisation also receives contributions towards costs for work done with international collaborative groups and from pharmaceutical companies for our own in-house Investigator Initiated Studies. Cancer Trials Ireland do not fundraise but from time to time individuals and groups of friends organise to donate to the work of the group. 2019 was a significant year in that respect thanks to the Friends of Cancer Trials Ireland and Friends of Pat Smullen and Horseracing Ireland.

The Finance Team reporting to the Audit Committee continue to update where necessary, all relevant finance policies and procedures.

#### **STATEMENT OF RISK MANAGEMENT**

Clinical trials can take up to 25 years to complete with the first 5 years being the most resource intensive period. In-house trials, trials which are initiated and led by Cancer Trial Ireland investigators, depend on grants from the HRB and Irish Cancer Society and funding from pharmaceutical companies which, due to the nature of trials, are spread over many years.

During 2019, Cancer Trials Ireland continue to implement decisions made by the Scientific Management Group (SMG) for new academic studies. The SMG open, close and on occasion have had to decline new trials in 2019 with important research questions due to funding requirements where we cannot cover all the costs. We continue to do more trials in partnership with international collaborative groups. These trials offer patients new treatment options. In addition, our clinicians continue to craft new research ideas and propose their studies to new partners and while some external partners can provide financial support to Cancer Trials Ireland, they cannot cover all the costs involved in sponsoring a clinical trial particularly a drug trial which is highly regulated. This is a common concern for academic clinical trials groups in Europe. The risk is academic groups like ours continue to lack ring-fenced core support, ideally from the State to enable our team at Cancer Trials Ireland to do the work and ask research questions relevant to the needs of patients. However, we are optimistic about the future with a new funding call on the horizon with the HRB which will support all clinical trials activity in Cancer Trials Ireland's central office.

#### **PLANS FOR FUTURE PERIOD**

Cancer Trials Ireland are ideally placed to succeed in the HRB call to be the Cancer Trials Network (2022-26). Given our track record of delivering clinical trial services and supports we plan to be successful in the bid. As the Cancer Clinical Trials Network we will continue to sponsor, oversee and support services to HRB hospital sites.

Cancer Trials Ireland has strengthened relationships with external organisations, including the HRB, Irish Cancer Society, National Cancer Control Programme (NCCP), Department of Health, the Clinical Research Facility Galway (CRFG), international collaborative groups, pharmaceutical companies, and other stakeholders such as the wider cancer research community, cancer patients and the public where possible.

The organisation will continue to act as an advocate for cancer trials and highlight its contribution not only in terms of fighting the battle against cancer but also its economic contribution.



**GOING CONCERN**

Subsequent to the financial year end, Ireland was impacted by the global COVID-19 virus pandemic. The directors considered the COVID-19 impact on the entity. The Entity's financial projections for the 2020 to 2021 financial year take into account the current COVID- 19 pandemic and the potential impact of it on the ability of the entity to continue as a going concern.

The entity has taken a series of actions aimed at safeguarding the entity's employees and business associates, including implementing a work-at-home policy. In addition, the Entity have initiated several proactive cost management strategies and cash conservation initiatives, including organisational and operating model efficiencies, hiring restrictions, reductions in third-party costs as well as other cost savings initiatives aimed at preserving cash. While the COVID-19 related disruptions are currently expected to be temporary, there is considerable uncertainty around the duration.

The entity had net current assets of €508,535 (2018: €384,421), including €4,130,470 (2018:€2,870,645) in cash at bank. Given the current financial position of the entity and the assets available to it, the ability to reduce activity levels if necessary and to implement cost saving initiatives should ensure that the entity is in at least a narrow deficit or small surplus position for 2020 and remain in a position to meets its liabilities as they fall due for the foreseeable future.

Having considered the above, the directors believe that it is appropriate to continue to adopt the going concern basis in preparing the financial statements and that there is a reasonable expectation that the Entity will continue to operate for the foreseeable future. The financial statements do not include any adjustments nor disclosures that would result if the Entity was unable to continue as a going concern.

**SUBSEQUENT EVENTS**

Subsequent to the financial year end Ireland has been impacted by the global Covid19 pandemic. However, given the unprecedented nature of the outbreak it is not yet possible to determine its full impact on results for the next full financial year.

The entity will continue to monitor the situation and take appropriate measures to adapt to ensure key services continue to be delivered. It is a non-adjusting post balance sheet event.

There are no other significant events subsequent to the financial year end.

## **CANCER TRIALS IRELAND CLG**

### **DIRECTORS' REPORT (CONTINUED) FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2019**

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#### **ACCOUNTING RECORDS**

The measures taken by the directors to ensure compliance with the requirements of Section 281 to 285 of the Companies Act 2014 with regards to keeping of accounting records, are the employment of appropriately qualified accounting personnel and the maintenance of computerised accounting systems. The company's accounting records are maintained at Innovation House, Old Finglas Road, Glasnevin, Dublin 11.

#### **DISCLOSURE OF INFORMATION TO AUDITORS**

In the case of each of the persons who are directors at the time the directors' report and financial statements are approved:

- a) So far as the director is aware, there is no relevant audit information of which the company's statutory auditors are unaware; and
- b) Each director has taken all steps that ought to have been taken by the director in order to make himself or herself aware of any relevant audit information and to establish that the company's auditors are aware of that information.

This confirmation is given and should be interpreted in accordance with the provisions of Section 330 of the Companies Act 2014 (as amended).

#### **AUDITORS**

The auditors, Deloitte Ireland LLP, Chartered Accountants and Statutory Audit Firm, continue in office in accordance with the provisions of Section 383(2) of the Companies Act, 2014.

Approved by the Board and signed on its behalf by:

Berchmans Gannon  
Director

Darren Byrne  
Director

Date: 9 October 2020

## CANCER TRIALS IRELAND CLG

### DIRECTORS' RESPONSIBILITIES STATEMENT

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The directors are responsible for preparing the directors' report and the financial statements in accordance with the Companies Act 2014.

Irish company law requires the directors to prepare financial statements for each financial year. Under the law, the directors have elected to prepare the financial statements in accordance with FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland issued by the Financial Reporting Council* ("relevant financial reporting framework"). Under company law, the directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the assets, liabilities and financial position of the company as at the financial year end date and of the profit or loss of the company for the financial year and otherwise comply with the Companies Act 2014.

In preparing those financial statements, the directors are required to:

- select suitable accounting policies for the Company Financial Statements and then apply them consistently;
- make judgements and estimates that are reasonable and prudent;
- state whether the financial statements have been prepared in accordance with the applicable accounting standards, identify those standards, and note the effect and the reasons for any material departure from those standards; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the company will continue in business.

The directors are responsible for ensuring that the company keeps or causes to be kept adequate accounting records which correctly explain and record the transactions of the company, enable at any time the assets, liabilities, financial position and profit or loss of the company to be determined with reasonable accuracy, enable them to ensure that the financial statements and directors' report comply with the Companies Act 2014 and enable the financial statements to be audited. They are also responsible for safeguarding the assets of the company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

## INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF CANCER TRIALS IRELAND CLG

### Report on the audit of the financial statements

#### Opinion on the financial statements of Cancer Trials Ireland CLG (the 'company')

In our opinion the financial statements:

- give a true and fair view of the assets, liabilities and financial position of the company as at 31 December 2019 and of the Surplus/Deficit for the financial year then ended; and
- have been properly prepared in accordance with the relevant financial reporting framework and, in particular, with the requirements of the Companies Act 2014.

The financial statements we have audited comprise:

- the Statement of Income and Retained Earnings;
- the Balance Sheet;
- the Statement of Cash Flows; and
- the related notes 1 to 20, including a summary of significant accounting policies as set out in note 2.

The relevant financial reporting framework that has been applied in their preparation is the Companies Act 2014 and FRS 102 "The Financial Reporting Standard applicable in the UK and Republic of Ireland" issued by the Financial Reporting Council ("the relevant financial reporting framework").

#### Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (Ireland) (ISAs (Ireland)) and applicable law. Our responsibilities under those standards are described below in the "*Auditor's responsibilities for the audit of the financial statements*" section of our report.

We are independent of the company in accordance with the ethical requirements that are relevant to our audit of the financial statements in Ireland, including the Ethical Standard issued by the Irish Auditing and Accounting Supervisory Authority, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Conclusions relating to going concern

We have nothing to report in respect of the following matters in relation to which ISAs (Ireland) require us to report to you where:

- the directors' use of the going concern basis of accounting in preparation of the financial statements is not appropriate; or
- the directors have not disclosed in the financial statements any identified material uncertainties that may cast significant doubt about the company's ability to continue to adopt the going concern basis of accounting for a period of at least twelve months from the date when the financial statements are authorised for issue.

#### Other information

The directors are responsible for the other information. The other information comprises the information included in the Directors' Report and Financial Statements for the financial year ended 31 December 2019 other than the financial statements and our auditor's report thereon. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

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## INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF CANCER TRIALS IRELAND CLG

### **Responsibilities of directors**

As explained more fully in the Directors' Responsibilities Statement, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view and otherwise comply with the Companies Act 2014, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the company or to cease operations, or have no realistic alternative but to do so.

### **Auditor's responsibilities for the audit of the financial statements**

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs (Ireland), we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.
- Conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of the auditor's report. However, future events or conditions may cause the entity (or where relevant, the group) to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that the auditor identifies during the audit.

This report is made solely to the company's members, as a body, in accordance with Section 391 of the Companies Act 2014. Our audit work has been undertaken so that we might state to the company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company and the company's members as a body, for our audit work, for this report, or for the opinions we have formed.

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## **INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF CANCER TRIALS IRELAND CLG**

### **Report on other legal and regulatory requirements**

#### **Opinion on other matters prescribed by the Companies Act 2014**

Based solely on the work undertaken in the course of the audit, we report that:

- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- In our opinion the accounting records of the company were sufficient to permit the financial statements to be readily and properly audited.
- The financial statements are in agreement with the accounting records.
- In our opinion the information given in the directors' report is consistent with the financial statements and the directors' report has been prepared in accordance with the Companies Act 2014.

#### **Matters on which we are required to report by exception**

Based on the knowledge and understanding of the company and its environment obtained in the course of the audit, we have not identified material misstatements in the directors' report.

We have nothing to report in respect of the provisions in the Companies Act 2014 which require us to report to you if, in our opinion, the disclosures of directors' remuneration and transactions specified by law are not made.

Margarita Martin  
For and on behalf of Deloitte Ireland LLP  
Chartered Accountants and Statutory Audit Firm  
Deloitte & Touche House, Earlsfort Terrace, Dublin 2

9 October 2020

**CANCER TRIALS IRELAND CLG****STATEMENT OF INCOME AND RETAINED EARNINGS  
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2019**

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	<i>Notes</i>	<b>2019</b> €	2018 €
<b>Income</b>	5	<b>3,690,403</b>	3,543,126
Expenditure		<b>(3,559,021)</b>	(3,442,452)
<b>Surplus on ordinary activities before interest</b>		<b>131,382</b>	<b>100,674</b>
Interest receivable and similar income	6	<b>3,928</b>	4,198
<b>SURPLUS FOR THE FINANCIAL YEAR</b>	7	<b>135,310</b>	104,872
RETAINED EARNINGS AT THE BEGINNING OF THE FINANCIAL YEAR		<b>398,604</b>	293,732
<b>RETAINED EARNINGS AT THE END OF THE FINANCIAL YEAR</b>		<b>533,914</b>	398,604

Income and expenditure are all derived from continuing operations.

**CANCER TRIALS IRELAND CLG****BALANCE SHEET AS AT 31 DECEMBER 2019**

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	<i>Notes</i>	<b>2019</b> €	2018 €
<b>Fixed Assets</b>			
Tangible assets	<i>11</i>	<b>25,379</b>	14,183
<b>Current Assets</b>			
Debtors	<i>12</i>	<b>2,906,087</b>	1,463,076
Cash and cash equivalents		<b>4,130,470</b>	2,870,645
		<b>7,036,557</b>	4,333,721
<b>Creditors:</b> Amounts falling due within one year	<i>13</i>	<b>(6,528,022)</b>	(3,949,300)
<b>Net Current Assets</b>		<b>508,535</b>	384,421
<b>Net Assets</b>		<b>533,914</b>	398,604
<b>Reserves</b>			
Retained earnings		<b>533,914</b>	398,604
		<b>533,914</b>	398,604

The financial statements were approved and authorised for issue by the Board of Directors on 9 October 2020 and signed on its behalf by:

Berchmans Gannon  
Director

Darren Byrne  
Director



**CANCER TRIALS IRELAND CLG**

**STATEMENT OF CASH FLOWS  
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2019**

<b>Reconciliation of (deficit)/surplus for the financial year to net cash flows from operating activities</b>	<i>Notes</i>	<b>2019 €</b>	2018 €
Surplus for the financial year		<b>135,310</b>	104,872
Adjustments for:			
Interest receivable and similar income	6	<b>(3,928)</b>	(4,198)
Depreciation	11	<b>15,158</b>	14,746
Loss on disposal of fixed assets	11	-	280
<b>Operating cash flows before movements in working capital</b>		<b>146,540</b>	115,700
(Increase)/decrease in debtors	12	<b>(1,443,011)</b>	386,313
Increase/(decrease) in creditors	13	<b>40,443</b>	(548,823)
Increase in fund balances	13	<b>2,538,279</b>	-
<b>Net cash flows from operating activities</b>		<b>1,282,251</b>	(46,810)
<b>Cash flows from investing activities</b>			
Interest received	6	<b>3,928</b>	4,198
Payments to acquire tangible fixed assets	11	<b>(26,354)</b>	(3,783)
<b>Net cash flows from investing activities</b>		<b>(22,426)</b>	415
<b>Net increase/ (decrease) in cash and cash equivalents</b>		<b>1,259,825</b>	(46,395)
Cash and cash equivalents at beginning of financial year		<b>2,870,645</b>	2,917,040
<b>Cash and cash equivalents at end of financial year</b>		<b>4,130,470</b>	2,870,645

**1. GENERAL INFORMATION**

Cancer Trials Ireland CLG (Registered number 268044) is a company limited by guarantee incorporated in the Republic of Ireland under Companies Act 2014. The address of the registered office and principal place of business is Innovation House, Old Finglas Road, Glasnevin, Dublin 11. The nature of the company's operations and its principal activities are set out in the Directors' Report on pages 3 to 9. The financial statements have been presented in Euro (€) which is also the functional currency of the company.

The change of company name was formally registered with the Companies Registration Office on 15 March 2018.

**2. ACCOUNTING POLICIES**

The significant accounting policies adopted by the company are summarised below. The accounting policies and measurement bases have all been applied consistently throughout the current and the preceding financial year.

**Statement of compliance**

The financial statements of the company for the year ended 31 December 2019 have been prepared on the going concern basis and in accordance with FRS 102 "The Financial Reporting Standard applicable in the UK and Republic of Ireland" (FRS 102).

**Basis of preparation**

The financial statements have been prepared on the going concern basis and in accordance with the historical cost convention. Historical cost is generally based on the fair value of the consideration given in exchange for assets. The financial reporting framework that has been applied in their preparation is the Companies Act 2014 and FRS 102 "The Financial Reporting Standard applicable in the UK and Republic of Ireland" issued by the Financial Reporting Council.

**Income**

In respect of research trials, when the outcome of a research contract cannot be estimated reliably, the company recognises revenue only to the extent of contract costs incurred that it is probable will be recovered, and the company recognises costs as an expense in the period in which they are incurred.

When it is probable that total research contract costs will exceed total contract revenue, the expected loss is recognised by the company immediately, with a corresponding provision for an onerous contract.

Grant income is recognised in the period in which there is entitlement, certainty of receipt and the amount can be measured with sufficient reliability. Income received relating to expense reimbursements is recorded once the claim has been agreed and the amount has been received. Income is deferred when monies are received in advance of the expenditure on the trials to which they relate.

Public donations and similar income arising from fundraising events are accounted for when received. As with many similar charitable organisations, independent groups from time to time organise fundraising activities. Where donations are given or pledged to specific purpose funds, the fund balance will reflect both cash received and receivables.

## 2. ACCOUNTING POLICIES (CONTINUED)

### Pensions

The company operates a defined contribution pension scheme. Pension contributions in respect of the scheme for employees, are charged to the income and expenditure account as they become payable in accordance with the rules of the scheme. The assets are held separately from those of the company in an independently administered fund. Differences between the amounts charged in the income and expenditure account and payments made to pension funds are treated as assets or liabilities.

### Taxation

The company is a registered charity and no provision is considered necessary for taxation.

### Tangible fixed assets and depreciation

Tangible fixed assets are stated at cost or at valuation, less accumulated depreciation. The charge to depreciation is calculated to write off the original cost or valuation of tangible fixed assets, less the estimated residual value, over their expected useful lives as follows:

Fixtures, fittings and equipment	-	15% Straight Line
Computer equipment	-	33% Straight Line

The carrying values of tangible fixed assets are reviewed annually for impairment in periods if events or changes in circumstances indicate the carrying value may not be recoverable.

### Foreign currencies

Monetary assets and liabilities denominated in foreign currencies are translated at the rates of exchange ruling at the Balance Sheet date. Non-monetary items that are measured in terms of historical cost in a foreign currency are translated at the rates of exchange ruling at the date of the transaction. Non-monetary items that are measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined. The resulting exchange differences are dealt with in the Income and Expenditure Account.

### Going Concern

The company's business activities, together with the factors likely to affect its future development, performance and position are set out in the directors' report. The directors' report describes the financial position of the company; its cash flows, liquidity position; the company's objectives, policies and processes for managing its capital; its financial risk management objectives. The company meets its day to day working capital requirements through accumulated reserves and cash in bank balances. The directors have a reasonable expectation that the company has adequate resources to continue in operational existence for the foreseeable future. They continue to adopt the going concern basis of accounting in preparing the annual financial statements. See further detail in note 3 below.

### Financial instruments

Financial assets and financial liabilities are recognised when the company becomes a party to the contractual provisions of the instrument. Financial liabilities are classified according to the substance of the contractual arrangements entered into. An equity instrument is any contract that evidences a residual interest in the assets of the company after deducting all of its liabilities.

The financial instruments are recognised and measured in accordance with Section 11 and Section 12 of FRS 102.

## 2. ACCOUNTING POLICIES (CONTINUED)

### *Financial assets and liabilities*

All financial assets and liabilities are initially measured at transaction price (including transaction costs), unless the arrangement constitutes a financing transaction. If an arrangement constitutes a finance transaction, the financial asset or financial liability is measured at the present value of the future payments discounted at a market rate of interest for a similar debt instrument. Financial assets and liabilities are only offset in the balance sheet when, and only when there exists a legally enforceable right to set off the recognised amounts and the company intends either to settle on a net basis, or to realise the asset and settle the liability simultaneously.

Financial assets are derecognised when and only when a) the contractual rights to the cash flows from the financial asset expire or are settled, b) the company transfers to another party substantially all of the risks and rewards of ownership of the financial asset, or c) the company, despite having retained some significant risks and rewards of ownership, has transferred control of the asset to another party and the other party has the practical ability to sell the asset in its entirety to an unrelated third party and is able to exercise that ability unilaterally and without needing to impose additional restrictions on the transfer.

Financial liabilities are derecognised only when the obligation specified in the contract is discharged, cancelled or expires. Balances that are classified as payable or receivable within one financial year on initial recognition are measured at the undiscounted amount of the cash or other consideration expected to be paid or received, net of impairment.

### **Leases**

Rentals under operating leases are charged on a straight-line basis over the lease term, even if the payments are not made on such a basis.

## 3. GOING CONCERN

Subsequent to the financial year end, Ireland was impacted by the global COVID-19 virus pandemic. The directors considered the COVID-19 impact on the entity. The Entity's financial projections for the 2020 to 2021 financial year take into account the current COVID-19 pandemic and the potential impact of it on the ability of the entity to continue as a going concern.

The entity has taken a series of actions aimed at safeguarding the entity's employees and business associates, including implementing a work-at-home policy. In addition the Entity have initiated several proactive cost management strategies and cash conservation initiatives, including organisational and operating model efficiencies, hiring restrictions, reductions in third-party costs as well as other cost savings initiatives aimed at preserving cash. While the COVID-19 related disruptions are currently expected to be temporary, there is considerable uncertainty around the duration.

The entity had net current assets of €508,535 (2018: €384,421), including €4,130,470 (2018:€2,870,645) in cash at bank of which €3,560,491 (2018: €1,865,442) is restricted. Given the current financial position of the entity and the assets available to it, the ability to reduce activity levels if necessary and to implement cost saving initiatives should ensure that the entity is in at least a narrow deficit or small surplus position for 2020 and remain in a position to meet its liabilities as they fall due for the foreseeable future.

Having considered the above, the directors believe that it is appropriate to continue to adopt the going concern basis in preparing the financial statements and that there is a reasonable expectation that the Entity will continue to operate for the foreseeable future. The financial statements do not include any adjustments nor disclosures that would result if the Entity was unable to continue as a going concern.

**NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)  
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2019**

**4. CRITICAL ACCOUNTING JUDGEMENTS AND KEY SOURCES OF ESTIMATION UNCERTAINTY**

In the application of the Company’s accounting policies, which are described in note 2, the directors are required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates. The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods.

In the opinion of the directors, there were no critical judgements, apart from those involving estimations (which are dealt with separately below), made in the process of applying the company’s accounting policies. The directors have assessed the going concern basis for the preparation of the financial statements which is detailed in note 2.

**Key source of estimation on uncertainty - Revenue recognition of research contracts**

In respect of research trials, the directors assess the probable recoverability of research contract costs incurred. In addition, if it is probable that total research contract costs will exceed total research contract revenue, the directors consider the value of such expected losses and recognise the provision under an onerous contract.

**5. INCOME**

The company's income is attributable to cancer research grants, clinical trials income and philanthropic contributions. All activities are carried out in the Republic of Ireland.

	<b>2019</b>	2018
	<b>€</b>	€
Grants	<b>1,916,321</b>	1,840,593
Study income	<b>1,510,663</b>	1,420,364
Donations and Fundraising	<b>263,419</b>	282,169
	<b><u>3,690,403</u></b>	<u>3,543,126</u>

**6. INTEREST RECEIVABLE AND SIMILAR INCOME**

	<b>2019</b>	2018
	<b>€</b>	€
Bank interest	<b>3,928</b>	4,198
	<b><u>3,928</u></b>	<u>4,198</u>

**CANCER TRIALS IRELAND CLG**

**NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)  
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2019**

**7. (DEFICIT)/SURPLUS FOR THE FINANCIAL YEAR**

	<b>2019</b>	2018
	<b>€</b>	€
(Deficit)/surplus for the financial year is stated after charging:		
Depreciation of tangible fixed assets	<b>15,158</b>	14,746
Directors' remuneration	-	-
Auditor's remuneration	<b>18,110</b>	18,450
Loss on disposal of fixed assets	-	280
	<u><u>                    </u></u>	<u><u>                    </u></u>

**8. EMPLOYEES AND REMUNERATION**

**Number of employees**

The average monthly number of persons employed during the financial year was as follows:

	<b>2019</b>	2018
	<b>Number</b>	Number
Office and administration	<b>48</b>	47
	<u><u>                    </u></u>	<u><u>                    </u></u>

The staff costs comprise:

	<b>2019</b>	2018
	<b>€</b>	€
Wages and salaries	<b>2,267,176</b>	2,147,242
Social insurance costs	<b>247,919</b>	231,517
Other retirement benefit costs	<b>68,414</b>	55,644
Redundancy costs	-	12,307
	<u><u>2,583,509</u></u>	<u><u>2,446,710</u></u>

The number of employees whose salaries (excluding employer pension contributions) were greater than €60,000 were as follows:

	<b>2019</b>	2018
	<b>Number</b>	Number
€60,001 - €70,000	<b>4</b>	6
€70,001 - €80,000	<b>3</b>	3
€80,001 - €90,000	<b>2</b>	2
€90,001 - €100,000	-	1
€100,001 - €110,000	<b>1</b>	1
	<u><u>                    </u></u>	<u><u>                    </u></u>

**NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)  
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2019**

**8. EMPLOYEES AND REMUNERATION (CONTINUED)**

The total remuneration package of the Chief Executive comprised of:

	<b>2019</b>	2018
	<b>€</b>	€
Wages and salaries	<b>106,000</b>	106,000
8% employer pension contribution	<b>8,480</b>	8,480
	<b>114,480</b>	114,480

**9. KEY MANAGEMENT COMPENSATION**

The total remuneration for key management personnel including pension contribution of €21,852 (2018: €22,911) and employer’s PRSI of €41,138 (2018: €43,033) for the financial year amounted to €438,678 (2018: €462,561) and this relates to 5 personnel (2018: 5).

**10. RELATED PARTY TRANSACTIONS**

Directors are not paid for any work undertaken on behalf of the company. However, the company’s funding contract with the Health Research Board (HRB) allows the company to use hospital funds to pay for substitute staff who enable our Clinical Lead to be released to support our studies. Currently both the Clinical Lead and Vice Clinical Lead are directors of the company.

Our payments to the directors’ employers in the current and prior financial year were as follows:

A payment of €107,000 (2018: €107,000) to the Royal College of Surgeons in Ireland (RCSI) in respect of Prof. Bryan Hennessy (Clinical Lead).

CANCER TRIALS IRELAND CLG

NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)  
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2019

11. TANGIBLE FIXED ASSETS

	Fixtures, fittings and equipment €	Computer equipment €	Total €
<b>Cost:</b>			
At 1 January 2019	2,309	119,354	121,663
Additions	2,420	23,934	26,354
<b>At 31 December 2019</b>	<b>4,729</b>	<b>143,288</b>	<b>148,017</b>
<b>Accumulated Depreciation:</b>			
At 1 January 2019	373	107,107	107,480
Charge for the year	464	14,694	15,158
<b>At 31 December 2019</b>	<b>837</b>	<b>121,801</b>	<b>122,638</b>
<b>Net book value:</b>			
<b>At 31 December 2019</b>	<b>3,892</b>	<b>21,487</b>	<b>25,379</b>
At 31 December 2018	1,936	12,247	14,183

12. DEBTORS

	2019 €	2018 €
Accrued income	1,252,687	750,248
Trade debtors	560,943	673,900
Prepayments	37,887	9,411
Fund Receivables	1,042,700	17,648
Other debtors	11,870	11,869
	<b>2,906,087</b>	1,463,076



**CANCER TRIALS IRELAND CLG**

**NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)  
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2019**

<b>13. CREDITORS:</b> Amounts falling due within one year	<b>2019</b>	2018
	<b>€</b>	€
Trade creditors	<b>129,359</b>	113,574
Taxation and social welfare (Note 14)	<b>1,130</b>	65,536
Creditor studies	<b>2,036,675</b>	1,941,124
Other creditors	<b>35,106</b>	6,041
Pension accrual	<b>17,213</b>	13,979
Onerous contracts provision	<b>550,080</b>	510,269
Accruals	<b>74,850</b>	73,076
Deferred income	<b>1,145,330</b>	1,225,701
Friends of Cancer Trials Ireland Fund	<b>94,415</b>	-
Pat Smullen Fund*	<b>2,443,864</b>	-
	<b>6,528,022</b>	3,949,300

\*The late Pat Smullen and Horse Racing Ireland approached Cancer Trials Ireland in the 2019 financial year to help raise funding for Cancer Trials Ireland and, in particular, pancreatic cancer trials. The public and friends of Horse Racing Ireland attending the events raised €2,526,901. As such these funds are restricted.

<b>14. TAXATION AND SOCIAL WELFARE</b>	<b>2019</b>	2018
	<b>€</b>	€
PAYE/PRSI	<b>1,130</b>	65,536

**15. FINANCIAL INSTRUMENTS**

The carrying value of the company's financial assets and liabilities are summarised by category below:

	<b>2019</b>	2018
	<b>€</b>	€
<b>Financial assets</b>		
<i>Measured at undiscounted amount receivable</i>		
• Accrued income (note 12)	<b>1,252,687</b>	750,248
• Trade debtors (note 12)	<b>603,643</b>	673,900
• Other debtors (note 12)	<b>11,870</b>	11,869
<b>Financial liabilities</b>		
<i>Measured at undiscounted amount payable</i>		
• Trade creditors (note 13)	<b>129,359</b>	113,574
• Creditor studies (note 13)	<b>2,036,675</b>	1,941,124
• Other creditors (note 13)	<b>35,106</b>	6,041
• Onerous provision (note 13)	<b>550,080</b>	510,269

**NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)  
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2019**

**16. STATUS**

The liability of the members is limited.

Every member of the company undertakes to contribute to the assets of the company in the event of it being wound up while they are members or within one year thereafter for the payment of the debts and liabilities of the company contracted before they ceased to be members and the costs, charges and expenses of winding up and for the adjustment of the rights of the contributors among themselves such amount as may be required, not exceeding €1.

**17. POST BALANCE SHEET EVENTS**

Subsequent to the financial year end Ireland has been impacted by the global Covid 19 pandemic. However, given the unprecedented nature of the outbreak it is not yet possible to determine its full impact on results for the next full financial year.

The organisation will continue to monitor the situation and take appropriate measures to adapt to ensure key services continue to be delivered. It is a non-adjusting post balance sheet event.

There are no other significant events subsequent to the financial year end.

**18. PENSION COSTS**

The company operates an occupational scheme, the assets of which are held by independent managers. The pension charge represents contributions paid or due by the company and amounted to €68,414 (2018: €55,644). There was an amount payable at the financial year end of €17,213 (2018: €13,979).

**19. OPERATING LEASE COMMITMENTS**

Total future minimum lease payments under non-cancellable operating lease are as follows:

	<b>Buildings 2019 €</b>	Buildings 2018 €
Amount due:		
Within one year	<b>142,440</b>	142,440
Between two and five years	<b>249,270</b>	391,710
After five years	-	-
<b>Total</b>	<b>391,710</b>	534,150

The lease is cancellable by either party by giving 9 months' notice except at the Break Option Date of 1st October 2020, when only two months' notice need be given.

**20. CONTINGENT LIABILITY**

Some trials continue patient treatment or follow up until there is a medical observation e.g. treatment to progression. Where such trials continue beyond the initial estimated time a contingent liability may arise which cannot be measured reliably.