

# Cancer Association of South Africa (CANSA)



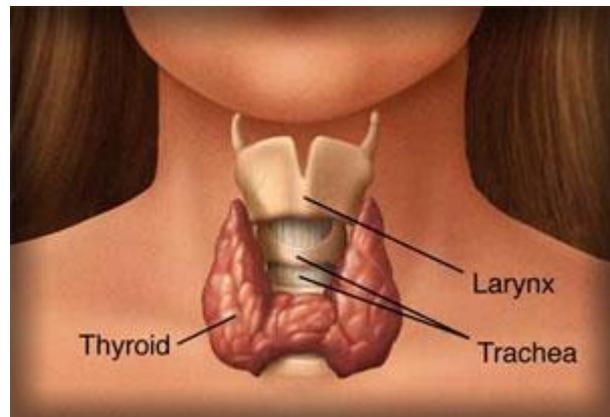
## Fact Sheet on Hürthle Cell Thyroid Cancer

### Introduction

Hürthle Cell Thyroid Cancer (Hürthle cell carcinoma and/or Hürthle cell adenoma) are usually classified with Follicular Thyroid Cancer, although it really is a distinct kind of tumour, making up about 3% of all thyroid cancer cases.

[Picture Credit: Thyroid]

A Hürthle Cell is a kind of thyroid cell that has a distinctive look: under the microscope it is bigger than a follicular cell and has pink-staining cellular material.



A Hürthle cell is a cell in the thyroid that is often associated with Hashimoto's thyroiditis as well as follicular thyroid cancer.



The Hürthle cell is named after German histologist Karl Hürthle (1860 – 1945), who investigated thyroid secretory function, particularly in dogs. However, this is a misnomer since Hürthle actually described parafollicular C cells. The cell known as the Hürthle cell was first described in 1898 by Max Askanazy, who noted it in patients with Graves' Disease. James Ewing first coined the term "Hürthle cell" in his 1919 oncology textbook in reference to the cell which Askanazy had first described. (Wikipedia; EndocrineWeb; New Health Advisor).

[Picture Credit: Karl Hürthle]

### Hürthle Cell Carcinoma

Like follicular tumours, there are benign Hürthle cell tumours and malignant Hürthle cell tumours, and the pathologist tells the difference between them based on invasion of the

capsule and the blood vessels. Benign Hürthle cell tumours are not a threat at all and should not come back once they are removed.

Hürthle cell cancer is considered a variant of follicular thyroid cancer. This version is a relatively rare form of differentiated thyroid cancer, accounting for only 3-10% of all differentiated thyroid cancers. Oncocytes in the thyroid are often called Hürthle cells. Although the terms oncocyte, oxyphilic cell, and Hürthle cell are used interchangeably, Hürthle cell is used only to indicate cells of thyroid follicular origin.

Hürthle Cell Carcinoma is a rare type of thyroid cancer that has a bad outlook. (EndocrineWeb; New Health Advisor; Wikipedia).

### Incidence of Hürthle Cell Carcinoma in South Africa

The National Cancer Registry (2012) does not provide any information on the incidence of Hürthle Cell Carcinoma in South Africa.

According to the National Cancer Registry (2012) the following number of cases of the thyroid gland was histologically diagnosed in South Africa during 2012:

Group - Males 2012	Actual No of Cases	Estimated Lifetime Risk	Percentage of All Cancers
All males	126	1:1 344	0,34%
Asian males	6	1:1 274	0,75%
Black males	22	1:5 274	0,19%
Coloured males	19	1:944	0,44%
White males	79	1:380	0,39%

Group - Females 2012	Actual No of Cases	Estimated Lifetime Risk	Percentage of All Cancers
All females	407	1:556	1,08%
Asian females	26	1:308	2,43%
Black females	126	1:1 305	0,76%
Coloured females	48	1:423	1,16%
White females	206	1:158	1,30%

The frequency of histologically diagnosed cases of cancer of the thyroid gland in South Africa for 2012 was as follows (National Cancer Registry, 2012):

Group - Males 2012	0 – 19 Years	20 – 29 Years	30 – 39 Years	40 – 49 Years	50 – 59 Years	60 – 69 Years	70 – 79 Years	80+ Years
All males	1	6	17	19	36	28	11	6
Asian males	0	0	1	3	1	1	0	0
Black males	0	1	3	0	7	7	0	1
Coloured males	0	0	2	5	8	2	1	0
White males	0	4	11	10	19	17	10	4

Group - Females 2012	0 – 19 Years	20 – 29 Years	30 – 39 Years	40 – 49 Years	50 – 59 Years	60 – 69 Years	70 – 79 Years	80+ Years
All females	3	34	65	101	82	65	41	13
Asian females	0	4	9	2	3	4	1	1
Black females	1	6	20	31	26	16	8	5
Coloured females	1	1	9	9	10	7	5	2
White females	1	18	23	53	37	30	22	3

N.B. In the event that the totals in any of the above tables do not tally, this may be the result of uncertainties as to the age, race or sex of the individual. The totals for 'all males' and 'all females', however, always reflect the correct totals.

## Symptoms of Hürthle Cell Carcinoma

Symptoms of Hürthle cell carcinoma are similar to those seen in other types of thyroid cancers.

The symptoms include:

- Appearance of a lump at the neck
- Voice change that does not get better
- Shortness of breath
- Sore throat
- Difficulty in swallowing
- Persistent cough which is not caused by a respiratory problem

Hürthle Cell Carcinoma complications include:

- Difficulty swallowing – when the tumour presses on the food pipe (oesophagus)
- Difficulty breathing – when the tumour presses on the windpipe (trachea)
- Spread of malignancy (metastasis) to other organs and tissues

(New Health Advisor; Mayo Clinic).

## Causes and Risk Factors for Hürthle Cell Carcinoma

It is not clear what causes Hürthle Cell Cancer.

Doctors know that cancer begins when a cell develops errors in its DNA - the genetic material that contains instructions for biochemical processes in one's body. When DNA is altered or damaged, these genes may not function properly, causing cells to grow out of control and eventually form a mass (tumour) of cancerous (malignant) cells.

Factors that increase the risk of developing Hürthle Cell Cancer include:

- Being female
- Being older
- Having a history of radiation treatments to the head and neck

(Mayo Clinic).

## Staging of Hürthle Cell Carcinoma

The extent, or stage of cancer, is used to determine the prognosis (i.e. the chance that a patient will recover, have a recurrence, or die of a disease) and the best treatment plan for an individual.

The stage of thyroid cancer is determined by the size of the largest tumour in the thyroid gland, whether it is confined to the thyroid gland, or if it has spread to other parts of the body (lymph nodes and distant sites).

The most common thyroid cancer staging system used is the TNM (**T**umour size, lymph **N**ode status, distant **M**etastasis).

The different parts of the TNM staging system are:

**Tumour size:**

**TX:** Primary tumour cannot be assessed

**T0:** No evidence of primary tumour

**T1:** 2 cm or smaller

**T2:** 2 to 4 cm

**T3:** > 4 cm or has grown a small amount just outside the thyroid

**T4a:** Any size tumour that has grown beyond the thyroid gland into nearby tissues of the neck

**T4b:** Any size that has grown back toward the spine or into nearby large blood vessels

**Lymph nodes:**

**NX:** Regional (nearby) lymph nodes cannot be assessed

**N0:** No spread to nearby lymph nodes

**N1:** Spread to nearby lymph nodes

**N1a:** Spread to lymph nodes next to the thyroid (central neck)

**N1b:** Spread to lymph nodes in the sides of the neck (lateral neck) or to the lymph nodes in the upper chest (mediastinal)

**Distant metastasis:**

**MX:** Presence of distant metastasis (spread) cannot be assessed

**M0:** No distant metastasis

**M1:** Distant metastasis is present, involving distant lymph nodes, internal organs, bones

Lower stages (i.e. I or II vs. III or IV) have a better overall prognosis for both survival and lower disease recurrence rates. The most important factor in staging thyroid cancer (papillary, follicular and Hürthle cell) is the patient's age. Patients who are younger than 45 years old at the time of diagnosis are a stage I no matter how large the tumour is or whether or not there are positive lymph nodes. If they are younger than 45 years old at the time of diagnosis and the cancer has spread to distant sites (i.e. metastasis), such as lungs, bones, or other organs, then they are considered stage II.

Patients older than 45 years at the time of diagnosis with papillary, follicular, and Hürthle cell thyroid cancers and all patients with medullary thyroid cancer, are staged as described below:

**Stage I (T1, N0, M0):** <2 cm across, with no spread to lymph nodes or distant sites.

**Stage II (T2, N0, M0):** 2 to 4 cm across, with no spread to lymph nodes or distant sites.

**Stage III (T3, N0, M0 or T1 to T3, N1a, M0)**

- The tumour is larger than 4 cm or has grown slightly outside the thyroid, but it has not spread to nearby lymph nodes or distant sites.
- The tumour is any size and has spread to lymph nodes around the thyroid in the neck (cervical nodes) but not to distant sites.

**Stage IVA (T4a, N0 to N1a, M0 or T1 to T4, N1b, M0):** One of the following applies:

- The tumour is any size and has grown beyond the thyroid gland to invade nearby tissues of the neck. It may or may not have spread to lymph nodes around the thyroid in the neck (central neck). It has not spread to distant sites.
- The tumour is any size and may have grown outside the thyroid gland. It has spread to lymph nodes in the side of the neck (lateral neck) or upper chest (mediastinal) but not to distant sites.

**Stage IVB (T4b, any N, M0):** The tumour is any size and has grown either into the spine or into nearby large blood vessels. It may or may not have spread to nearby lymph nodes, but it has not spread to distant sites.

**Stage IVC (any T, any N, M1):** The tumour is any size and may or may not have grown outside the thyroid. It may or may not have spread to nearby lymph nodes, but it has spread to distant sites.

In addition to the TNM staging system there have been other staging systems used which also accurately predict the risk of tumour recurrence and prognosis for thyroid cancer. Nonetheless, **TNM** staging is used by the World Health Organization (WHO). (The American Association of Endocrine Surgeons).

### **Treatment of Hürthle Cell Carcinoma**

Treatment can be medical, surgical or radiation therapy or a combination of two or more regimens:

#### Surgical Treatment

Surgery is the main treatment for patients with Hürthle cell carcinoma. Surgical treatment is aimed at removal of the entire cancer, thereby minimising the risk of locally persistent or recurrent disease, providing adequate staging information, minimising risk without compromise to optimal cancer management, improving efforts for postoperative adjunctive treatment (e.g., radioactive iodide), and facilitating follow-up care.

Total thyroidectomy is usually recommended for patients with Hürthle cell carcinomas, whereas patients with Hürthle cell adenomas are generally treated with a thyroid lobectomy.

Although total thyroidectomy is generally considered the treatment of choice for Hürthle cell carcinoma, a lobectomy is usually performed first; if histologic sections show Hürthle cell carcinoma, as evidenced by vascular and/or capsular invasion, then a complete thyroidectomy is performed in a second surgery.

In clinically high-risk cases and in some institutions, a total thyroidectomy is performed as the first surgery based on frozen section results. Unfortunately, the majority of series have insufficient patient numbers to allow statistically valid conclusions regarding which of these approaches should become the standard.

Standard surgical wound care is usually appropriate. Patients should be monitored carefully for postoperative infection, hematoma, signs of recurrent laryngeal nerve injury (e.g., hoarseness), respiratory compromise, and signs of hypoparathyroidism and hypocalcemia.

### Medical Treatment

Surgical excision is the main treatment for patients with Hürthle cell carcinoma. Postoperative iodine-131 (<sup>131</sup>I) scanning is usually performed 4-6 weeks after surgery. No thyroid hormone treatment is administered to the patient in the interim. If uptake occurs in the thyroid bed or other sites, a treatment dose of <sup>131</sup>I is administered, and another total body scan is obtained 4-7 days later.

- Radioactive iodine-131 treatment - This treatment is usually administered if postoperative iodine scanning shows uptake, in the thyroid bed or elsewhere.

<sup>131</sup>I therapy is used after surgery for three reasons. First, radioactive iodide destroys any remaining normal thyroid tissue, thereby enhancing the sensitivity of subsequent <sup>131</sup>I total-body scanning and increasing the specificity of measurements of serum thyroglobulin for the detection of persistent or recurrent disease. Second, <sup>131</sup>I therapy may destroy occult microscopic carcinoma. Third, the use of a large amount of <sup>131</sup>I allows for total-body scanning, which is a more sensitive test for detecting persistent carcinoma.

Compared with other thyroid carcinomas, Hürthle cell cancer has a lower avidity for <sup>131</sup>I; therefore, treatment with radioactive iodide has limited efficacy. Reportedly, approximately 10% of metastases take up radioiodine, compared with 75% of metastases from follicular carcinoma; thus, radioactive iodide treatment, which is the most useful nonsurgical therapy for recurrent well-differentiated thyroid carcinoma, is not always useful in patients with Hürthle cell carcinoma. This causes difficulty in the treatment of recurrences. Nevertheless, radioactive iodide treatment is used for most patients with Hürthle cell cancers after total and near-total thyroidectomy and in the treatment of patients with recurrent and metastatic Hürthle cell carcinoma.

There is limited evidence in the literature that redifferentiation therapy with retinoic acid may restore <sup>131</sup>I uptake in some thyroid carcinomas that have lost their capability for radioiodine concentration; however, the benefits of this approach remain uncertain. Retinoic acid therapy also may be considered in patients with Hürthle cell carcinoma that does not take up radioactive iodide, although this is not yet a standard form of therapy.

- Levothyroxine treatment - The growth of thyroid tumour cells is controlled by thyroid-stimulating hormone (TSH), and the inhibition of TSH secretion with levothyroxine (T4) lowers recurrence rates and improves survival; therefore, T4 should be administered to all patients with thyroid carcinoma, regardless of the extent of thyroid surgery and other treatments.

Levothyroxine treatment is started after the treatment dose of <sup>131</sup>I is administered. The effective dose of T4 in adults is 2.2-2.8 mcg/kg; children require higher doses. The adequacy of therapy is monitored by measuring serum TSH about 8-12 weeks after the treatment begins. The initial goal is a serum TSH concentration of 0.1 µU/mL or less and a serum triiodothyronine concentration within the reference range. When these guidelines are followed, T4 therapy does not have deleterious effects on the heart or bone.

- Chemotherapy - Chemotherapy for metastatic differentiated thyroid cancer is usually ineffective. However, some experimental trials have yielded promising results.

Over the past decade, good progress has been made in understanding molecular mechanisms of thyroid cancer; accordingly, multiple medications are being developed to target various molecules involved in the development of differentiated thyroid cancer. These targets are present both in the tumour cell as well as at the vascular endothelial cells providing blood supply to the tumour. The drugs include multikinase inhibitors, selective kinase inhibitors, and combination therapies. Examples include sorafenib, gefitinib, axitinib, motesanib, sunitinib, and pazopanib. Sorafenib is approved by the US Food and Drug Administration (FDA) for advanced differentiated thyroid cancer.

Younes, *et al.*, (2006) have studied antivasular therapy in mouse models with bone metastasis from follicular thyroid cancer. In these studies, a novel dual tyrosine kinase inhibitor of epidermal growth factor receptor (EGFR), vascular endothelial growth factor (VEGFR) was used alone and in combination with paclitaxel. These studies showed suppression of tumour growth, with promising outcomes.

### Radiation Therapy

External radiotherapy - Hürthle cell carcinoma is considered a radiosensitive tumour. Radiation therapy may provide palliative relief from symptomatic metastases, control recurrent tumours, and prevent recurrence of advanced resected tumours.

External radiotherapy to the neck and mediastinum is indicated only in patients in whom surgical excision is incomplete or impossible. This therapy can also be considered for tumours that do not take up <sup>131</sup>I. (Medscape).

### **About Clinical Trials**

Clinical trials are research studies that involve people. These studies test new ways to prevent, detect, diagnose, or treat diseases. People who take part in cancer clinical trials have an opportunity to contribute to scientists' knowledge about cancer and to help in the development of improved cancer treatments. They also receive state-of-the-art care from cancer experts.

### Types of Clinical Trials

Cancer clinical trials differ according to their primary purpose. They include the following types:

Treatment - these trials test the effectiveness of new treatments or new ways of using current treatments in people who have cancer. The treatments tested may include new drugs or new combinations of currently used drugs, new surgery or radiation therapy techniques, and vaccines or other treatments that stimulate a person's immune system to fight cancer. Combinations of different treatment types may also be tested in these trials.

Prevention - these trials test new interventions that may lower the risk of developing certain types of cancer. Most cancer prevention trials involve healthy people who have not had cancer; however, they often only include people who have a higher than average risk of developing a specific type of cancer. Some cancer prevention trials involve people who have

had cancer in the past; these trials test interventions that may help prevent the return (recurrence) of the original cancer or reduce the chance of developing a new type of cancer

Screening - these trials test new ways of finding cancer early. When cancer is found early, it may be easier to treat and there may be a better chance of long-term survival. Cancer screening trials usually involve people who do not have any signs or symptoms of cancer. However, participation in these trials is often limited to people who have a higher than average risk of developing a certain type of cancer because they have a family history of that type of cancer or they have a history of exposure to cancer-causing substances (e.g., cigarette smoke).

Diagnostic - these trials study new tests or procedures that may help identify, or diagnose, cancer more accurately. Diagnostic trials usually involve people who have some signs or symptoms of cancer.

Quality of life or supportive care - these trials focus on the comfort and quality of life of cancer patients and cancer survivors. New ways to decrease the number or severity of side effects of cancer or its treatment are often studied in these trials. How a specific type of cancer or its treatment affects a person's everyday life may also be studied.

#### Where Clinical Trials are Conducted

Cancer clinical trials take place in cities and towns in doctors' offices, cancer centres and other medical centres, community hospitals and clinics. A single trial may take place at one or two specialised medical centres only or at hundreds of offices, hospitals, and centres.

Each clinical trial is managed by a research team that can include doctors, nurses, research assistants, data analysts, and other specialists. The research team works closely with other health professionals, including other doctors and nurses, laboratory technicians, pharmacists, dieticians, and social workers, to provide medical and supportive care to people who take part in a clinical trial.

#### Research Team

The research team closely monitors the health of people taking part in the clinical trial and gives them specific instructions when necessary. To ensure the reliability of the trial's results, it is important for the participants to follow the research team's instructions. The instructions may include keeping logs or answering questionnaires. The research team may also seek to contact the participants regularly after the trial ends to get updates on their health.

#### Clinical Trial Protocol

Every clinical trial has a protocol, or action plan, that describes what will be done in the trial, how the trial will be conducted, and why each part of the trial is necessary. The protocol also includes guidelines for who can and cannot participate in the trial. These guidelines, called eligibility criteria, describe the characteristics that all interested people must have before they can take part in the trial. Eligibility criteria can include age, sex, medical history, and current health status. Eligibility criteria for cancer treatment trials often include the type and stage of cancer, as well as the type(s) of cancer treatment already received.

Enrolling people who have similar characteristics helps ensure that the outcome of a trial is due to the intervention being tested and not to other factors. In this way, eligibility criteria help researchers obtain the most accurate and meaningful results possible.

### National and International Regulations

National and international regulations and policies have been developed to help ensure that research involving people is conducted according to strict scientific and ethical principles. In these regulations and policies, people who participate in research are usually referred to as “human subjects.”

### Informed Consent

Informed consent is a process through which people learn the important facts about a clinical trial to help them decide whether or not to take part in it, and continue to learn new information about the trial that helps them decide whether or not to continue participating in it.

During the first part of the informed consent process, people are given detailed information about a trial, including information about the purpose of the trial, the tests and other procedures that will be required, and the possible benefits and harms of taking part in the trial. Besides talking with a doctor or nurse, potential trial participants are given a form, called an informed consent form, that provides information about the trial in writing. People who agree to take part in the trial are asked to sign the form. However, signing this form does not mean that a person must remain in the trial. Anyone can choose to leave a trial at any time—either before it starts or at any time during the trial or during the follow-up period. It is important for people who decide to leave a trial to get information from the research team about how to leave the trial safely.

The informed consent process continues throughout a trial. If new benefits, risks, or side effects are discovered during the course of a trial, the researchers must inform the participants so they can decide whether or not they want to continue to take part in the trial. In some cases, participants who want to continue to take part in a trial may be asked to sign a new informed consent form.

New interventions are often studied in a stepwise fashion, with each step representing a different “phase” in the clinical research process. The following phases are used for cancer treatment trials:

### Phases of a Clinical Trial

Phase 0. These trials represent the earliest step in testing new treatments in humans. In a phase 0 trial, a very small dose of a chemical or biologic agent is given to a small number of people (approximately 10-15) to gather preliminary information about how the agent is processed by the body (pharmacokinetics) and how the agent affects the body (pharmacodynamics). Because the agents are given in such small amounts, no information is obtained about their safety or effectiveness in treating cancer. Phase 0 trials are also called micro-dosing studies, exploratory Investigational New Drug (IND) trials, or early phase I trials. The people who take part in these trials usually have advanced disease, and no known, effective treatment options are available to them.

Phase I (also called phase 1). These trials are conducted mainly to evaluate the safety of chemical or biologic agents or other types of interventions (e.g., a new radiation therapy technique). They help determine the maximum dose that can be given safely (also known as the maximum tolerated dose) and whether an intervention causes harmful side effects. Phase I trials enrol small numbers of people (20 or more) who have advanced cancer that cannot be treated effectively with standard (usual) treatments or for which no standard treatment exists. Although evaluating the effectiveness of interventions is not a primary goal of these trials, doctors do look for evidence that the interventions might be useful as treatments.

Phase II (also called phase 2). These trials test the effectiveness of interventions in people who have a specific type of cancer or related cancers. They also continue to look at the safety of interventions. Phase II trials usually enrol fewer than 100 people but may include as many as 300. The people who participate in phase II trials may or may not have been treated previously with standard therapy for their type of cancer. If a person has been treated previously, their eligibility to participate in a specific trial may depend on the type and amount of prior treatment they received. Although phase II trials can give some indication of whether or not an intervention works, they are almost never designed to show whether an intervention is better than standard therapy.

Phase III (also called phase 3). These trials compare the effectiveness of a new intervention, or new use of an existing intervention, with the current standard of care (usual treatment) for a particular type of cancer. Phase III trials also examine how the side effects of the new intervention compare with those of the usual treatment. If the new intervention is more effective than the usual treatment and/or is easier to tolerate, it may become the new standard of care.

Phase III trials usually involve large groups of people (100 to several thousand), who are randomly assigned to one of two treatment groups, or “trial arms”: (1) a control group, in which everyone in the group receives usual treatment for their type of cancer, or 2) an investigational or experimental group, in which everyone in the group receives the new intervention or new use of an existing intervention. The trial participants are assigned to their individual groups by random assignment, or randomisation. Randomisation helps ensure that the groups have similar characteristics. This balance is necessary so the researchers can have confidence that any differences they observe in how the two groups respond to the treatments they receive are due to the treatments and not to other differences between the groups.

Randomisation is usually done by a computer program to ensure that human choices do not influence the assignment to groups. The trial participants cannot request to be in a particular group, and the researchers cannot influence how people are assigned to the groups. Usually, neither the participants nor their doctors know what treatment the participants are receiving.

People who participate in phase III trials may or may not have been treated previously. If they have been treated previously, their eligibility to participate in a specific trial may depend on the type and the amount of prior treatment they received.

In most cases, an intervention will move into phase III testing only after it has shown promise in phase I and phase II trials.

Phase IV (also called phase 4). These trials further evaluate the effectiveness and long-term safety of drugs or other interventions. They usually take place after a drug or intervention has been approved by the medicine regulatory office for standard use. Several hundred to several thousand people may take part in a phase IV trial. These trials are also known as post-marketing surveillance trials. They are generally sponsored by drug companies.

Sometimes clinical trial phases may be combined (e.g., phase I/II or phase II/III trials) to minimize the risks to participants and/or to allow faster development of a new intervention.

Although treatment trials are always assigned a phase, other clinical trials (e.g., screening, prevention, diagnostic, and quality-of-life trials) may not be labelled this way.

### Use of Placebos

The use of placebos as comparison or “control” interventions in cancer treatment trials is rare. If a placebo is used by itself, it is because no standard treatment exists. In this case, a trial would compare the effects of a new treatment with the effects of a placebo. More often, however, placebos are given along with a standard treatment. For example, a trial might compare the effects of a standard treatment plus a new treatment with the effects of the same standard treatment plus a placebo.

### Possible benefits of taking part in a clinical trial

The benefits of participating in a clinical trial include the following:

- Trial participants have access to promising new interventions that are generally not available outside of a clinical trial.
- The intervention being studied may be more effective than standard therapy. If it is more effective, trial participants may be the first to benefit from it.
- Trial participants receive regular and careful medical attention from a research team that includes doctors, nurses, and other health professionals.
- The results of the trial may help other people who need cancer treatment in the future.
- Trial participants are helping scientists learn more about cancer (e.g., how it grows, how it acts, and what influences its growth and spread).

### Potential harms associated with taking part in a clinical trial

The potential harms of participating in a clinical trial include the following:

- The new intervention being studied may not be better than standard therapy, or it may have harmful side effects that doctors do not expect or that are worse than those associated with standard therapy.
- Trial participants may be required to make more visits to the doctor than they would if they were not in a clinical trial and/or may need to travel farther for those visits.

### Correlative research studies, and how they are related to clinical trials

In addition to answering questions about the effectiveness of new interventions, clinical trials provide the opportunity for additional research. These additional research studies, called correlative or ancillary studies, may use blood, tumour, or other tissue specimens (also known as ‘biospecimens’) obtained from trial participants before, during, or after treatment. For example, the molecular characteristics of tumour specimens collected during a trial

might be analysed to see if there is a relationship between the presence of a certain gene mutation or the amount of a specific protein and how trial participants responded to the treatment they received. Information obtained from these types of studies could lead to more accurate predictions about how individual patients will respond to certain cancer treatments, improved ways of finding cancer earlier, new methods of identifying people who have an increased risk of cancer, and new approaches to try to prevent cancer.

Clinical trial participants must give their permission before biospecimens obtained from them can be used for research purposes.

#### When a clinical trial is over

After a clinical trial is completed, the researchers look carefully at the data collected during the trial to understand the meaning of the findings and to plan further research. After a phase I or phase II trial, the researchers decide whether or not to move on to the next phase or stop testing the intervention because it was not safe or effective. When a phase III trial is completed, the researchers analyse the data to determine whether the results have medical importance and, if so, whether the tested intervention could become the new standard of care.

The results of clinical trials are often published in peer-reviewed scientific journals. Peer review is a process by which cancer research experts not associated with a trial review the study report before it is published to make sure that the data are sound, the data analysis was performed correctly, and the conclusions are appropriate. If the results are particularly important, they may be reported by the media and discussed at a scientific meeting and by patient advocacy groups before they are published in a journal. Once a new intervention has proven safe and effective in a clinical trial, it may become a new standard of care. (National Cancer Institute).

#### **Medical Disclaimer**

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