Cancer Association of South Africa (CANSA)

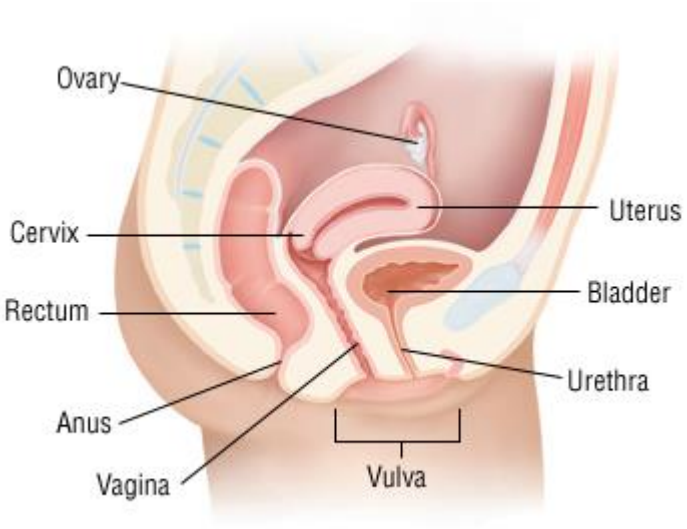
Research • Educate • Support

Fact Sheet on Melanoma of the Vulva and Vagina

Introduction

The vagina or birth canal is the opening through which menstrual fluid leaves a woman's body and babies are born. It is connected to the cervix, which is the opening of the uterus or womb, and the vulva (folds of skin around its opening).

Usually, the vagina is in a collapsed position with its walls touching. The walls have many folds that allow the vagina to open and expand during sexual intercourse and vaginal childbirth. The vaginal lining is kept moist by mucus released from glands in the cervix.



[Picture Credit: Female Genitalia]

The vaginal walls have a thin layer of cells called the epithelium, which contains cells called squamous epithelial cells. The vaginal wall, underneath the epithelium, is made up of connective tissue, involuntary muscle tissue, lymph vessels, and nerves.

Melanoma of Female Genitalia

Melanoma is a cancer that starts in cells called melanocytes. Melanocytes are pigment producing cells. They are mostly found in the skin. Most melanomas develop in parts of the body that are exposed to the sun. But one can get them anywhere, including in body organs, because there are melanocytes in those areas too. That is why one sometimes hears melanoma of the skin called cutaneous melanoma. Cutaneous means of the skin. It is still not clear why melanomas can form in parts of the body that are not exposed to the sun.

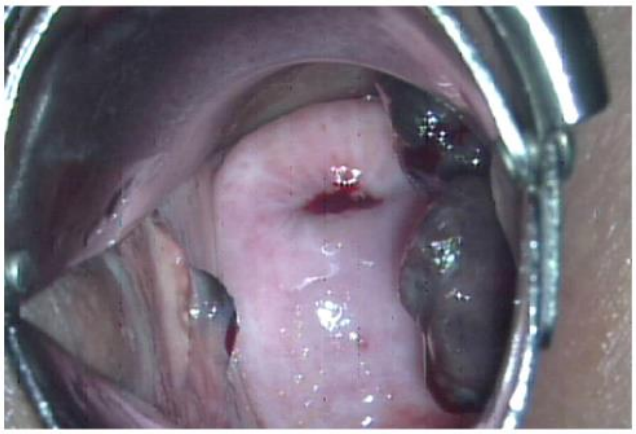
Even though some melanomas grow in parts of the body that does not see the sun, it is still very important to remember that the best way to keep one's risk of melanoma or other skin cancers as low as possible is to avoid being in the sun too much. It is extremely important to

look after one's skin and report any signs or symptoms of skin cancer to one's doctor immediately.

If someone has melanoma in an unusual site such as genital skin or inside the nose or sinuses, the treatment should be planned by a multidisciplinary team (MDT). The team should include skin melanoma specialists and surgeons and oncologists who normally treat genital cancer or cancers inside the nose and sinuses.
(Cancer Research UK; Cancer.Net).

Incidence of Melanoma of the Female Genitalia
The National Cancer Registry (2012) does not provide any information regarding melanoma of the female genitalia.

Melanoma of the Vagina and Vulva
In this Fact Sheet melanoma of the vagina and vulva will be discussed together under the heading of cancer of the vagina.



[Picture Credit: Vaginal melanoma]

It is not clear what causes vaginal cancers. In general, cancer begins when healthy cells acquire a genetic mutation that turns normal cells into abnormal cells. Healthy cells grow and multiply at a set rate, eventually dying at a set time. Cancer cells grow and multiply out of control, and they do not die. The accumulating abnormal cells form a mass (tumour).

Cancer cells invade nearby tissues and can break off from an initial tumour to spread elsewhere in the body (metastasise).

Vaginal cancer is divided into different types based on the type of cell where the cancer began. Vaginal cancer types include:

- Vaginal squamous cell carcinoma, which begins in the thin, flat cells (squamous cells) that line the surface of the vagina, is the most common type
- Vaginal adenocarcinoma, which begins in the glandular cells on the surface of your vagina
- Vaginal melanoma, which develops in the pigment-producing cells (melanocytes) of your vagina
- Vaginal sarcoma, which develops in the connective tissue cells or muscles cells in the walls of your vagina
- Clear cell adenocarcinoma, which occurs in women whose mothers took the drug diethylstilbestrol (DES) during pregnancy between the late 1940s and 1971. It is estimated that one woman out of 1 000 women exposed to DES will develop vaginal cancer.

(Mayo Clinic; Cancer.Net).

Signs and Symptoms of Vaginal Cancer
Women with vaginal cancer may experience the following symptoms or signs. Sometimes, women with vaginal cancer do not show any of these symptoms. Or, these symptoms may be caused by a medical condition that is not cancer.
The most common symptom of vaginal cancer is abnormal vaginal bleeding. Vaginal bleeding, during or after menopause, is not normal and is a sign of a problem. Other symptoms of vaginal cancer include:

- Abnormal vaginal discharge
- Difficulty or pain when urinating
- Pain during sexual intercourse
- Pain in the pelvic area (the lower part of the abdomen between the hip bones)
- Pain in the back or legs
- Swelling in the legs
- Unusual vaginal bleeding, for example, after intercourse or after menopause.
- Watery vaginal discharge.
- A lump or mass in the vagina.
- Painful urination.
- Constipation.
- Pelvic pain

If a woman is concerned about one or more of the symptoms or signs on this list, she must please talk with a doctor. The doctor will ask how long and how often she has been experiencing the symptom(s), in addition to other questions. This is to help find out the cause of the problem.

If cancer is diagnosed, relieving symptoms remains an important part of cancer care and treatment. This may also be called symptom management, palliative care, or supportive care. Be sure to talk with the health care team about symptoms experienced, including any new symptoms or a change in symptoms.
(Cancer.Net; Mayo Clinic).

Types of Vaginal Cancer
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(Mayo Clinic).

Staging of Vaginal Cancer

The TNM and International Federation of Gynaecology and Obstetrics (FIGO) classifications for staging vaginal cancer are provided below (see Tables 1 and 2)

The TNM and FIGO Staging for Vaginal Cancer

Primary tumour (T)

TNM	*FIGO*	*Definition*
TX		Primary tumour cannot be assessed
T0		No evidence of a primary tumour
Tis*		Carcinoma in situ (pre-invasive)
T1	I	Tumour confined to the vagina
T2	II	Tumour invades paravaginal tissues but does not extend to pelvic wall
T3	III	Tumour extends to pelvic wall†
T4	IVA	Tumour invades mucosa of the bladder or rectum or shows direct extension beyond the true pelvis; bullous oedema is not sufficient to allow classification as T4

Regional lymph nodes (N)

TNM	*FIGO*	*Definition*
NX		Regional lymph nodes cannot be assessed
N0		No regional lymph node metastasis
N1	III	Regional (pelvic or inguinal) lymph node metastasis

Distant metastasis (M)

TNM	*FIGO*	*Definition*
M0		No distant metastasis
M1	IVB	Distant metastasis

* FIGO no longer includes stage 0 (Tis).

† Pelvic wall is defined as muscle, fascia, neurovascular structures, or skeletal portions of the bony pelvis. On rectal examination, there is no cancer-free space between the tumour and pelvic sidewalls.

Anatomic Stage/Prognostic Groups

Stage	**TNM**		
0*	Tis	N0	M0
I	T1	N0	M0
II	T2	N0	M0
III	T1-T3 T3	N1 N0	M0
IVA	T4	Any N	M0
IVB	Any T	Any N	M1

* FIGO no longer includes stage 0.

Rules of staging include the following:

- As with cervical cancer, FIGO uses clinical staging for vaginal cancer because many patients do not undergo surgical management for this condition; the clinical stage of vaginal cancer must not be changed because of subsequent findings once treatment has started
- In cases treated with a definitive surgical procedure, the pathology findings should not be allowed to change the clinical staging, but they may be recorded as the pathologic staging of disease; the pTNM classification of the American Joint Committee on Cancer (AJCC) is appropriate for this purpose, as described in the tables above
- All data available before the initiation of definitive treatment can and should be used to determine the clinical stage of vaginal cancer; these data include all imaging studies and the results of biopsies or fine-needle aspiration of lymph nodes
- When there is doubt about the stage to which a particular case should be allocated, the lesser stage should be used
- Suspected involvement of the bladder or rectal mucosa must be confirmed by means of biopsy
- According to FIGO, cases with clinical involvement of the cervix or the vulva should be classified as primary cervical or vulvar cancers, respectively; tumours limited to the urethra should be classified as urethral cancers

(Medscape).

Treatment of Vaginal Cancer by Stage
VAIN (vaginal intraepithelial neoplasia) – VAIN is not cancer, but there are areas of abnormal cells in the lining of the vagina that could become cancerous. Some doctors call it pre-cancer.

VAIN is graded as VAIN 1, 2, or 3. VAIN 1 means that one third of the thickness of the surface layer of the vaginal lining contains abnormal cells. VAIN 3 means the full thickness of the lining of the vagina has abnormal cells.

Women who have VAIN 1 do not usually need any treatment. The cancerous cells often disappear after a while. The doctor will arrange regular check-ups to make sure this has happened.
If a woman has VAIN 2 or 3 the doctor may recommend treating the abnormal cells. This aims to prevent cancer developing. These include:

- Laser treatment
- Surgery
- Creams
- Radiotherapy

Laser treatment - A laser is a very strong, hot beam of light that burns away the abnormal cells. Your doctor will use local anaesthetic to numb the area. Several biopsies may also be taken before the laser treatment. The doctor sends the biopsy samples to the laboratory so that the cells can be examined.

Surgery – The patient may have surgery, especially if the abnormal cells have come back or the patient has had a hysterectomy in the past. The doctor may cut out the abnormal cells and some surrounding healthy tissue. This is called a wide local excision. The doctor sends the tissue to the laboratory and a pathologist looks at the cells under a microscope.
Sometimes the surgeon removes the area of abnormal cells with a small loop of wire that has an electric current. This is called loop diathermy or LEEP. It can cut out tissue and stop bleeding at the same time. The surgeon also removes a surrounding area of healthy tissue to lower the risk of the abnormal cells coming back.

Creams - Creams are not standard treatment for VAIN and are usually used as part of clinical trials. Imiquimod cream (Aldara) is a newer cream being tested for VAIN. It is an antiviral drug that boosts the immune system to destroy the abnormal cells.

Sometimes a chemotherapy cream is used, usually fluorouacil. But this needs to be applied often and can irritate the delicate skin of the vagina. So it is not used very often.

Radiotherapy - One might have radiotherapy if the precancerous cells have come back after treatment. Or one may have it if the abnormal cells are in several areas of the vagina. Radiotherapy is not commonly used and is not a standard treatment for VAIN. A patient usually has this as internal radiotherapy (brachytherapy). This means a radioactive object called a source is put inside the vagina, to treat the local area. A patient may have this treatment over several hours or a few days.

Stage 1 vaginal cancer

Radiotherapy is the first treatment for many women with squamous cell or adenocarcinoma stage 1 vaginal cancers. Internal radiotherapy is used to treat small tumours on the inner lining of the vagina. If the tumour is in the deeper vaginal tissues then external radiotherapy may be used as well. The patient may also have chemotherapy treatment alongside radiotherapy.

Some women with stage 1 cancer need to have surgery. If the cancer is on the upper part of the vagina it is sometimes necessary to remove the womb Uterus). This operation is called radical hysterectomy. The patient will have lymph nodes removed from around the womb and part of the vagina taken away (radical partial vaginectomy).
If the cancer is in the lower or middle part of the vagina, the patient may need to have the whole of the vagina removed (total vaginectomy). The surgeon may then surgically make a new vagina for the patient. This is called vaginal reconstruction. The patient will probably have external radiotherapy after surgery to try to make sure that any cancer cells left behind are destroyed.

Doctors are trying to develop a new treatment for women who are young and want to keep their fertility. It involves removing less vaginal tissue than usual and then having internal radiotherapy. The research so far seems to show that this will be as successful as radical surgery or very high doses of radiotherapy for treating cancer of the vagina. But it is not standard treatment at the moment.

Stage 2, 3 and 4A vaginal cancer

Stage 2, 3 and 4A vaginal cancer are all treated in a similar way. Radiotherapy is the main treatment and usually both internal radiotherapy and external radiotherapy are used. The patient may also have chemotherapy treatment alongside radiotherapy.

The patient might be offered surgery if she has had previous radiotherapy treatment to the pelvic area. There is a limit to the amount of radiotherapy one can have to any one part of the body. Too much can cause damage to healthy tissues. In rare cases, the doctor may suggest that the patient has an operation to move the bowel out of the radiotherapy treatment area to protect it. A patient would normally only need to have this done in the following situations:

- If particularly high radiotherapy doses are needed
- The patient has had surgery to the bowel in the past, which has left her with internal scar tissue called adhesions

Stage 4B vaginal cancer

Stage 4B means that the cancer has spread to another part of the body. This stage is not usually curable, but radiotherapy can relieve symptoms such as pain, swelling or bleeding. The specialist may suggest chemotherapy if the patient is fit enough to have the treatment. If there is a suitable clinical trial running, the specialist may ask the patient to join it. The specialist will only suggest this if they know that the patient would receive suitable treatment within the trial. Vaginal cancer is rare and so it is quite difficult to research. Taking part in the trial may help to improve treatment in the future for other women with vaginal cancer.

Vaginal melanoma

Surgery is the main treatment for vaginal melanoma. Radiotherapy and chemotherapy generally do not work well for melanoma. Because this type of vaginal cancer is so rare, it has been difficult to find out which type of surgery is the best. The aim of the surgery is to remove all of the melanoma cells. But doctors do not know if they need to remove the whole of the vagina, or whether it is just as good to remove only the melanoma, with a surrounding border of healthy tissue that is free of cancer cells. This border is called a healthy margin. It also is not clear how many lymph nodes they need to remove.

Future research may lead to smaller operations for this type of cancer.
(Cancer Research UK).

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.

<u>Use of Placebos</u>

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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