

Clinical Trials and Breast Cancer



Mission

EUROPA DONNA — The European Breast Cancer Coalition is an independent, non-profit organisation whose members are affiliated groups from throughout Europe. The Coalition works to raise awareness of breast cancer and to mobilise the support of European women in pressing for improved breast cancer education, appropriate screening, optimal treatment and care and increased funding for research. EUROPA DONNA represents the interests of European women regarding breast cancer to local and national authorities as well as to institutions of the European Union.

This booklet addresses two of EUROPA DONNA's 10 Goals: to ensure that all women understand fully any proposed treatment options, including entry into clinical trials and their right to a second opinion; and to promote the advancement of breast cancer research. Furthermore, according to the Brussels statement on breast cancer from the 2nd European Breast Cancer Conference: “Randomised clinical trials represent the most effective way of evaluating new therapies but also offer treatment opportunities. Obstacles to the participation for both patients and clinicians should be as low as possible.”

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About clinical trials

Controlled clinical trials are the safest way to evaluate new medicines and procedures that may be more valuable in predicting and treating breast cancer. Many women feel that they receive better medical care when they participate in a clinical trial. Both healthy women and women with breast cancer can participate in clinical trials. EUROPA DONNA — The European Breast Cancer Coalition promotes awareness and dissemination of information about clinical trials but does not recruit patients for any specific trial. Any medical decision should be discussed with your doctor.

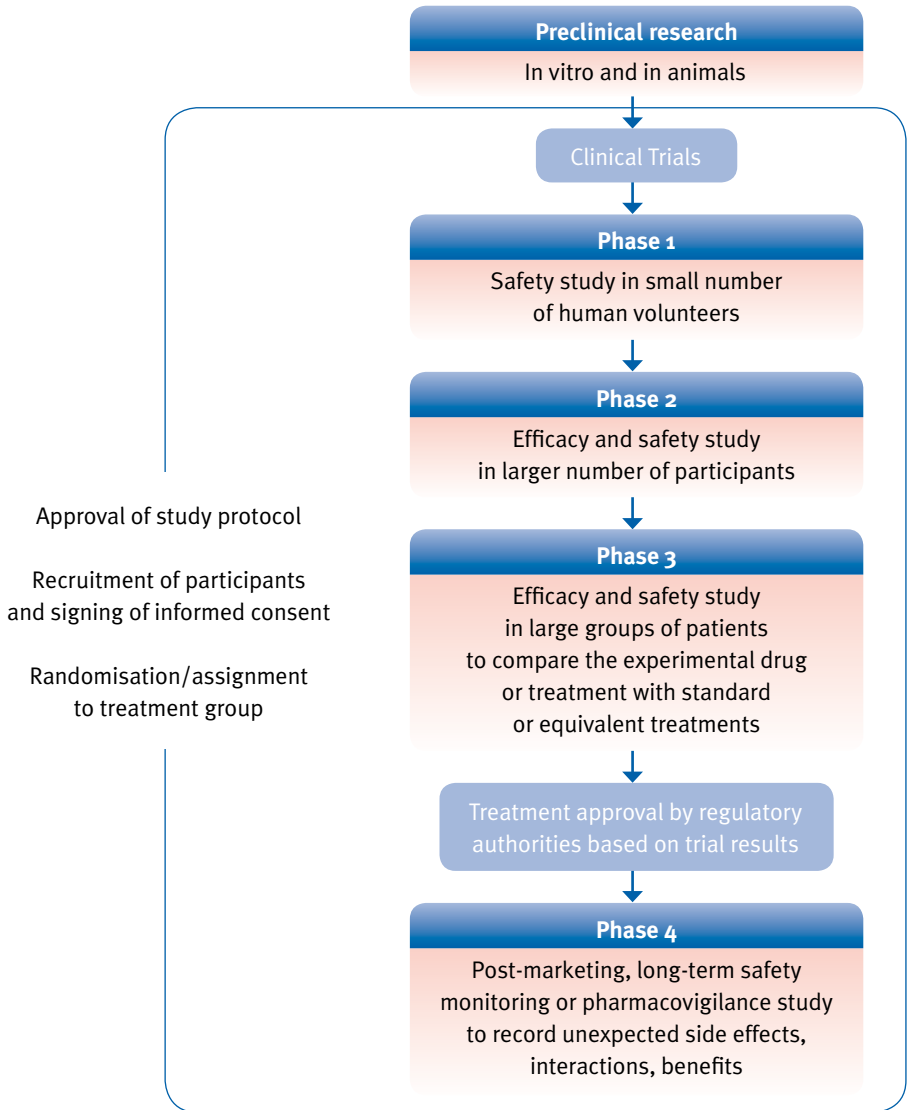
What is a clinical trial?

Many different kinds of studies are conducted to better understand the nature of breast cancer. A breast cancer study is not necessarily a clinical trial. **A cancer clinical trial is a study done with human subjects to try a new therapy, procedure or method for preventing, diagnosing or treating cancer.** In order to proceed in the clinical trial process the new treatment must have demonstrated significant potential to work better than existing methods.

Clinical trials with humans are begun only after **laboratory** (in vitro) and **animal studies** have shown that the new therapy is safe and effective. Each type of clinical trial is designed to answer a specific set of questions. There are different phases of clinical research; each phase is also designed to answer a specific set of questions. If the results of a trial are satisfactory, a new trial is designed to answer the questions for the next phase.

Treatment trials test a new therapy (a drug, surgical procedure or radiation therapy, hormone therapy, gene therapy, or a combination of these therapies) to treat cancer. **Diagnostic trials** aim to identify better tests or procedures for diagnosing a particular type of cancer. **Prevention trials** test a new method to lower the risk of a type of cancer occurring. **Screening trials** test ways to diagnose cancer sooner, in the early stages of the disease. **Quality of life (QoL) trials** examine ways to support cancer patients and their families and to improve their comfort and enhance their quality of life.

A **Phase 1** trial studies a very small number of volunteers to assess the new treatment's safety for humans and to evaluate side effects. Participants can be healthy volunteers or patients with advanced cancer for whom there is no effective standard treatment. This part of the study investigates the best method to deliver the new treatment (e.g., by mouth or injection) and to identify the maximum tolerated dose. A **Phase 2** trial continues to evaluate safety, and it determines how effective the treatment is. A **Phase 3** trial studies the new treatment's efficacy compared to standard, existing treatment(s). Phase 3 trials enrol large numbers of participants; each person is usually assigned by chance (randomised selection) to use the standard treatment(s) or the new treatment. Researchers may also conduct follow-up studies, sometimes referred to as **Phase 4** trials. This type of study examines additional long-term effects of a screening method or treatment. Pharmaceutical company studies of this type are known as post-market research.



Should I participate in a clinical trial?

As with all issues regarding health and medical care, the decision to take part in a clinical trial should be reviewed carefully and completely with a **health care provider**. For breast cancer patients it is important to learn as much as possible about the specific type of breast cancer, the diagnosis and available treatments and new therapies under investigation.

Who conducts a clinical trial?

A clinical trial is guided by a **principal investigator**. The principal investigator for a breast cancer clinical trial should be a medical doctor with valid experience in breast oncology research. A **research team**, composed of other doctors, scientists, nurses, psychologists and medical and research professionals, supports the principal investigator. Many diverse specialists contribute to the trial design and the results analysis.

Who sponsors clinical trials?

Different organisations, agencies and companies may be involved in a single trial. For example, the study may be guided by a team of researchers and funded by resources from a public health agency, a not-for-profit organisation and/or a private pharmaceutical or biotechnology company. Often private sponsors are interested in commercialising the results of clinical trials. A woman should request a clear explanation of the role of each sponsor before deciding to enrol in a particular trial.

How are clinical trial participants protected?

In order for a **study protocol** to be approved for a cancer clinical trial the research team must ascertain that each procedure within the trial follows **internal and international guidelines**. Most reputable public and private research institutions have an **Institutional Review Board (IRB)**, or a form of it sometimes referred to as an **Ethics Committee (EC)**. The purpose of an IRB/EC is to ensure that trials are conducted safely, ethically and with full patient consent. The IRB/EC is an independent group that oversees the actions and documents related to the clinical trial; it is composed of medical specialists, nurses, social workers, medical ethicists and patient advocates. The institution may also have a series of **standard operating procedures (SOP)** concerned with different aspects of a trial.

In developing the study protocol the research team must follow the guidelines established by the World Medical Association **Declaration of Helsinki**. The document, subtitled “Ethical Principles for Medical Research Involving Human Subjects”, states that “considerations related to the well-being of the human subject should take precedence over the interests of science and society.” Clinical trials performed in the European Union are required to be conducted in accordance with **good clinical practice guidelines** as described in the **EU Clinical Trials Regulation** EU No. 536/2014. The Regulation ensures greater harmonisation of the rules for conducting clinical trials throughout the EU. The authorisation procedure is based on a single submission via a single EU portal, an assessment procedure resulting in a single decision, rules on the protection of subjects and informed consent, and transparency requirements. The European Commission expects this Regulation to be fully effective in 2019 once the EU Clinical Trials Portal and Database has been finalised. **Individual countries** may also have legislation pertaining to medical research standards; this information should be available from the Ministry of Health and professional medical associations in each country. The participating clinics and doctors’ offices may also have a policy similar to a “**Patients’ Bill of Rights**”. Before enrolling in a clinical trial it is a good idea to request a copy of these documents and any others specific to a country.

In a clinical trial it is essential that the participants and research team actively communicate as much as possible so that the study results are reliable. The **Informed Consent process** has been designed to foster good communication between the participant and the research team and to ensure that each participant is fully aware of her commitment and rights. This process begins with supplying information about the trial to persons who are interested in taking part in the study. An eligible, prospective participant meets with a member of the research team, who should be willing to provide a copy of the study protocol or a concise version of the protocol. The research team member will also provide the **Informed Consent document**. This document explains facts about the trial, such as its purpose, duration, required or alternative procedures and tests, benefits and risks. A prospective participant then takes as much time as is necessary to read and comprehend the document and consider her decision. She may want to discuss the trial details with her doctor and family members. If she is a breast cancer patient, she may want to speak with a member of a breast cancer patient support and advocacy group.

In order to be useful, data collected from a clinical trial must be analysed and interpreted. Of particular interest may be the **right to privacy** and how that right will be guaranteed by subsequent use of the information gathered during the trials. The new EU Clinical Trials Regulation requires all information stored in the EU database to be publicly available, with a few exceptions such as personal data. International standards and national regulations stipulate that all health data collected for research purposes is to remain **confidential**. The EU General Data Protection Regulation (GDPR) implemented in 2018 sets out that any request for consent must be provided in a clear, intelligible, and easily accessible form. The purpose for data collection and processing needs to be attached to that consent. The consent form should include a specific authorisation for access to the trial information for persons other than members of the research team for reasons besides health care decisions. Clinical trial participants are usually asked to sign a number of documents. It is essential for the participant and the research team to understand what is expected of them. The researchers may need to collect a substantial amount of information during the trial, some of which may involve medical tests and exams. The type of treatment and procedures and how often each will be administered should be clearly explained. The frequency and number of tests and medical exams that will be necessary must be established before enrolment.

When a woman decides to participate she needs to sign the **Informed Consent document** to confirm that she understands the trial and will collaborate. She should keep a copy of the Informed Consent document in the event of future questions. If this document needs to be modified during the trial the participant will be asked to sign the amended document. Once the participant is enrolled in the trial, the conditions and rights concurred in the Informed Consent document continue for the participant. The participant may receive updates about the study, which could affect her decision to stay in the trial. If the treatment is discovered to cause harm, her participation in the study will be immediately discontinued. The participant knows that she is **free to leave the trial at any time**. Upon leaving the trial, a woman is free to make her treatment decisions based on what she and her doctor feel is best.

What are the requirements for participation?

Because every clinical trial is designed to answer a very specific set of questions, the **eligibility criteria** for participating in a given trial are also very specific. A breast cancer clinical trial is interested in enrolling patients with particular types of cancer at certain stages. The study may also be interested in other patient characteristics such as age, health history, treatment history or genetic factors.

Compared to routine care, participation in a clinical trial often requires additional tests and more frequent contact with medical personnel; these conditions may be necessary for an extended period of time. It is extremely important that individuals who choose to participate in a clinical trial reliably follow the instructions, abide by the treatment schedule, attend medical appointments, and record all additional information required by the researchers.

What are the possible risks?

Every woman considering participation in a breast cancer clinical trial needs to understand that the purpose of most clinical trials is to **test a new treatment or practice against already existing methods**. Often the new treatment or practice is tested in several different trials comparing variations of the new therapy or examining combinations of the new therapy with existing therapies. In cancer clinical trials a **placebo** (a treatment, such as a sugar tablet, that does not add therapeutic benefits) is not usually given unless it is administered along with a treatment proven to be effective. This may be the case in a co-therapy study, where the existing treatment and placebo are tested against the existing treatment with a new treatment. Sometimes subsequent trials (Phase 2 or Phase 3) demonstrate that the new treatment or procedure would be a better therapeutic choice for a specific group of women, depending on their health history and type of breast cancer. The physical side effects (**adverse events**) of a new treatment may be greater or lesser than those associated with existing treatments. Some long-term risks may be unknown during the initial trials; these factors are examined in follow-up studies.

In addition to considering the physical impact of a new treatment or practice in breast cancer research, there are **social and financial issues** to address. A clinical trial may require different tests and/or a different method of delivering the treatment as compared to the standard practice. Questions about personal time management and leave from work should be discussed with the research team, personal physician and one's own family.

Different trials and different countries have varying approaches to covering the **cost of clinical trial participation**. Some trials provide reimbursement to physicians and hospitals for the costs associated with collecting medical information and administering medical tests. There may be a reimbursement for participants in recognition of their effort. A clearly written explanation of the research team's responsibility and involvement with health care costs and claims should be given to the participant. A woman should

discuss the arrangements for the financial responsibility regarding the costs for care during the clinical trial as well as any possible future care with the research team contact person and with her insurance providers.

What are the possible benefits?

By taking part in a clinical trial, participants are followed very closely by doctors involved in breast cancer research and treatment. Research has shown that many women feel that they have received **superior medical care** while taking part in a clinical trial. If a new therapy shows superior benefits to existing methods then the study subjects may be the first to have access to and benefit from the new treatment or practice. Some clinical trials have been halted early because the treatment benefits were so clear that all parties involved felt it necessary to make the treatment available to as many cancer patients as soon as possible. The tamoxifen trial is an example of such an outcome; trastuzumab was also fast-tracked by regulators based on benefits seen in clinical trials. Clinical trials can also be halted early if no benefit is detected with the trial drug. Participating in a clinical trial for breast cancer is one of the ways to contribute to the effort to find better ways of preventing, detecting and treating breast cancer.

How does the enrolment process work?

The research team carefully considers the **eligibility criteria** for a trial. These requirements are included in the study protocol and brought to the Institutional Review Board (IRB/EC) for approval. In order for researchers to be certain that the results obtained in a clinical trial are truly due to the new treatment and not the result of chance or other factors, the trial must enrol a sufficient number of participants. In the case of Phase 3 trials and follow-up studies many participants are usually needed (100 to several thousand). Sometimes the research team publicises the study and directly enrolls participants. In other cases the research team co-operates with medical personnel in doctors' offices and clinics in order to find and screen participants. A sponsoring pharmaceutical company may provide information via publications and websites about the study. Sometimes patient advocacy groups provide information about breast cancer studies or assist with the enrolment process. Private health care firms may provide enrolment services for financial reimbursement.

European legislation requires that an individual must give **written consent** when providing personal information. Although a participant's identity is never disclosed and the data are protected by EU data protection legislation, a participant may not know which specific professionals, institutions or companies may eventually have access to the information given in the enrolment process. It is very important that a prospective participant consider this before providing any information. She may want to discuss this issue with a member of the research team before supplying additional personal information. Even though many women may not be eligible for or may not complete a particular trial the general information gathered may be analysed for the study results.

How can women find specific trials for breast cancer?

After a woman has discussed her interest in clinical trials with her **health care provider** and she has reviewed the available information on specific types of trials, she can consult different **listings of clinical trials**. Her doctor may have experience with a particular type of trial or with a specific treatment. A hospital department for patient advocacy, breast health or oncology may have information readily available. Some trials are listed on the websites of non-profit organisations and public health agencies. Other websites are commercially sponsored; the site owners or sponsors potentially receive some financial gain when a person uses those sites to find a clinical trial. Enrolment information for breast cancer clinical trials in Europe is available on a number of websites. These sites offer patient-directed pages about specific trials, including the name and telephone number of a contact person on the research team. There are also pages for doctors containing more clinical information, so that a woman and her doctor may evaluate the eligibility and participation requirements together. It is essential that trials be registered and that results are reported and available to the public. In this regard, the new EU Clinical Trials Regulation will require summaries of clinical trial results to be produced and disseminated in lay language.

The World Health Organization (WHO) has established the **International Clinical Trials Registration Platform** (www.who.int/ictrp) as a major initiative aimed at standardising the way information on medical studies is made available to the public. The Registry Platform sets international norms and standards for trial registration and reporting that uphold scientific and ethical principles.

When **Clinical Trials Regulation** EU No. 536/2014 officially comes into effect, it will include an EU portal and database of clinical trials to be set up and maintained by the European Medicines Agency (EMA). The portal will be the single entry point for submitting clinical trial information in the EU. Members of the public will be able to use the website to access detailed information on all clinical trials conducted in the EU, in all official EU languages. Some of the website features will include:

- An overview of clinical trial statistics
- An advanced search
- Downloadable data and reports
- Site updates and announcements
- Lay summaries of clinical trial results

This will replace the EU Clinical Trials Register website (<https://www.clinicaltrialsregister.eu>), which in the meantime can be used to access information on all clinical trials commencing in the European Community from 1 May 2004 onwards.

In the United States, the US National Library of Medicine, which is part of the National Institutes of Health, provides the **ClinicalTrials.gov** website. This gives access to a database of privately and publicly funded clinical studies conducted around the world. It can be searched by country, condition or disease, or drug name, among others. It can also specifically search for studies that are recruiting patients. Study details include the location (eg, clinic or hospital) where the trial is being run and a description of the protocol, study aims and eligibility criteria to participate in the study. Results can be consulted on the page once they are available.

Ten steps to finding a clinical trial (adapted from the National Cancer Institute)

1. Understand clinical trials (by reading this booklet and other key resources)
2. Talk with your doctor about your options
3. Know as much about your cancer as possible so that you know if you meet the eligibility criteria of a trial. See the NCI Cancer Details Checklist. (<https://www.cancer.gov/about-cancer/treatment/clinical-trials/search/trial-guide/detailschecklist.pdf>)
4. Search for the appropriate clinical trial on sites such as the EU clinical trials portal and clinicaltrials.gov
5. Search other sources for clinical trials, such as research organisations, drug and biotech companies or advocacy groups (See Resources for further trial information at the end of this booklet)
6. Take a closer look at the potential clinical trials, including key factors such as the trial objective, eligibility criteria, the location and the length of the study
7. Contact the clinical trial team directly or through your doctor
8. Ask the trial co-ordinator questions about the trial (see the questions below)
9. Before making a final decision, discuss your options with your doctor
10. If you decide to participate, schedule an appointment with the trial team

For the full National Cancer Institute Steps to Find a Clinical Trial see: www.cancer.gov/clinicaltrials/learningabout/treatment-trial-guide

What should a woman know and ask before deciding to participate in a clinical trial?

Will my doctor help me evaluate a potentially appropriate clinical trial by reviewing the study protocol with me?

How will participation in a trial affect my current care?

How will my doctor monitor my care if I decide to participate in a trial?

Will my doctor help me evaluate ongoing concerns about my participation?

Will my doctor have any direct contact with the study investigators?

What type of breast cancer is the study investigating?

What type of clinical trial is this study?

What is the aim of the study?

What are the requirements for participation?

What are the study treatments?

Where will I undergo treatment in the study?

Who is sponsoring this clinical trial?

How are participants assigned to different treatment groups in the study?

Can I choose to be in a specific group within the study?

How many people will participate in the study?

How long does the study last?

What happens at the end of the trial?

How will the results be presented?

What are the short- and long-term potential benefits?

What are the potential short- and long-term risks?

What are the possible effects of the treatment on my family and social life?

Will the treatment affect my fertility?

Will the treatment affect my ability to work?

What medical tests will be given and how often?

What information will be collected and how often?

What kind of long-term follow-up does the trial involve?

What can I do if I don't feel well during the study?

What happens if I decide to leave the trial early?

Who pays for the cost of my care during the trial?

What are the conditions of patient privacy for this study?

Who will have access to the information gathered in the study?

Will other people have access to that information in the future?

Resources for further trial information

Breast International Group. www.breastinternationalgroup.org

EU Clinical Trials Regulation No 536/2014.

https://ec.europa.eu/health/human-use/clinical-trials/regulation_en

EU Clinical Trials Register. <https://www.clinicaltrialsregister.eu>

European Medicines Agency (EMA). www.ema.europa.eu

European Organization for Research and the Treatment of Cancer (EORTC).

<https://www.eortc.org>

International Breast Cancer Study Group (IBCSG). www.ibcsg.org

National Cancer Institute, U.S. Department of Health and Human Services.

www.cancer.gov/clinicaltrials

World Health Organization (WHO), International Clinical Trials Registry Platform (ICTRP). www.who.int/ictrp/en

Other helpful resources

- Council for International Organizations of Medical Sciences, World Health Organization, Geneva. International Ethical Guidelines For Biomedical Research Involving Human Subjects. www.cioms.ch (Translations available)
- European Commission, Directorate General for Health & Consumers. Clinical Trials. (Available online: http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm)
- European Commission. Clinical Trials Regulation EU No 536/2014 (Available online: https://ec.europa.eu/health/human-use/clinical-trials/regulation_es)
- International Conference on Harmonisation. Good Clinical Practice Guideline E6(R1), 1996. (Available online: www.ich.org)
- National Cancer Institute, National Institutes of Health. Taking Part in Cancer Treatment Research Studies. (Available online: www.cancer.gov/clinicaltrials/learningabout/Taking-Part-in-Cancer-Treatment-Research-Studies)
- National Institutes of Health. Steps to Find a Clinical Trial. (Available online: www.cancer.gov/clinicaltrials/learningabout/treatment-trial-guide)
- National Institutes of Health. NIH Clinical Research Trials and You. (Available online: www.nih.gov/health/clinicaltrials)
- World Health Organization, The Importance of Pharmacovigilance – Safety Monitoring of Medicinal Products. (Available online: <http://apps.who.int/medicinedocs/en/d/Js4893e/5.html>)
- World Medical Association. World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. Adopted by the 18th WMA General Assembly Helsinki, June 1964. Last amended by the 59th WMA General Assembly, Seoul, Korea, October 2008. (Available online: www.wma.net)

Glossary

- Adjuvant chemotherapy:** An anti-cancer drug given in addition to another type of treatment, such as surgery or radiation therapy.
- Adverse event:** Any untoward medical occurrence in a patient; it is not necessarily due to treatment.
- Combination therapy:** Using two or more treatments at once.
- Comparator:** A product or placebo used as a reference in a clinical trial.
- Control group:** A group of participants in a clinical study who receive the standard treatment against which the study medication will be compared.
- Controlled trial:** A trial in which the product being investigated is compared to a reference treatment or placebo.
- Crossover:** A comparison of at least two treatments in which subjects are switched to the alternative treatment after a specified period of time.
- Data Monitoring Committee:** A group of independent, external experts that assesses a trial's progress, and data on safety and efficacy, if applicable.
- Double-blind study:** When both the study participants and the research team are unaware which medication has been administered in order to reduce bias.
- Eligibility criteria:** Requirements that a person must meet in order to be able to participate in a clinical study, such as age, type and stage of cancer, general health and previous treatment.
- Ethics Committee:** At all health care facilities, a designated group of scientists, doctors, consumers and other individuals that reviews and approves the protocol for a clinical trial (see Institutional Review Board).
- Informed consent:** A process required in all clinical trials, whereby a patient is told of the aims and details of a clinical trial in order to be able to voluntarily decide whether or not to participate. It involves the participant signing an informed consent document.
- Institutional Review Board:** At all health care facilities, a designated group of scientists, doctors, consumers and other individuals that reviews and approves the protocol for a clinical trial (see Ethics Committee).
- ISRCTN number:** An International Standard Randomised Controlled Trial Number (ISRCTN) is an eight-digit number used to identify clinical trials worldwide.
- In vitro study:** Experiments undertaken in test tubes or cell culture.
- In vivo study:** Experiments undertaken in animals.
- Maximum tolerated dose:** Determined by testing increasing doses, this is the highest dose of a drug or treatment that does not cause unacceptable side effects.
- Multimodal therapy:** Using a combination of treatment methods, e.g., radiotherapy and chemotherapy.
- Neoadjuvant therapy:** Administering a treatment before the main therapy is undertaken, e.g., chemotherapy before surgery.

Overall survival rate: The percentage of people who are alive for a designated period of time (e.g., 5 years) after they were diagnosed with or treated for a disease, such as breast cancer.

Parallel group: When a trial evaluates two or more treatments at the same time in separate groups of subjects.

Pharmacodynamic study: A study that explores the effect a medicine has on the body.

Pharmacogenetic study: A study investigating a genetic variation that leads to differing responses to drugs.

Pharmacokinetic study: A study that explores what the body does to a medicine.

Placebo: An inert preparation administered in a controlled trial to measure the effect of an active substance.

Primary endpoint: Established before the study begins, this is the main result that is measured at the end of a study to determine if a given treatment worked (e.g., progression-free survival).

Progression-free survival: The length of time during and after treatment in which a patient is living with a disease and it does not get worse. It is often used in a clinical study to help determine how well a new treatment has worked.

Protocol: The outline, design or plan to be followed in a study.

Randomisation: The process by which trial participants are assigned to treatment groups by chance rather than by choice in order to reduce bias.

Study arm: A segment of a study where participants receive the same treatment, e.g., the control arm or the active treatment arm.

Single-blind study: When study participants are unaware which medication they are being administered, in order to reduce bias.

Translational research: When the results of research done in the laboratory, clinical or population studies are used to develop new ways to diagnose and treat disease (e.g., using a bench-to-bedside approach). Research can also be conducted with the aim of enhancing best treatment practices.

Please see the EUROPA DONNA website for individual country information:
www.europadonna.org

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EUROPA DONNA – The European Breast Cancer Coalition

Piazza Amendola, 3
20149 Milan, Italy
Tel: +39 02 3659 2280
Fax: +39 02 3659 2284
info@europadonna.org
www.europadonna.org



Kingdom Belarus Belgique България Ceská Republika Dan
z Respublikası Kypros Latvija Leituva Luxembourg Mako