Understanding Clinical Trials for Secondary Breast Cancer

The Patient Trial Advocate Service (PTA) from Make 2nds Count

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Registered charity SC048268

Introducing Make 2nds Count

Make 2nds Count is a UK-wide patient and family focused charity dedicated to giving hope to women and men living with secondary breast cancer.

We strive to do this by raising awareness and funding medical research that will contribute to advancing an increased quality of life for patients. Our community programme supports patients and families affected by this incurable disease, which is also known as metastatic breast cancer.

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What Are Clinical Trials?

Clinical trials are regulated and scientifically based medical research studies. They are usually conducted by a team of doctors, nurses, universities and sometimes pharmaceutical companies. Clinical trials are closely inspected and ethically approved before any patients are allowed to be approached to take part in a trial. This is to make sure patients are cared for safely and reduce any potential risks as much as possible.

Clinical trials for secondary breast cancer might study a wide range of treatments.

- Drug treatments related to chemotherapy, hormone medications, targeted therapies and immunotherapy
- Treatments such as surgery or radiotherapy
- Blood and tissue samples from past biopsies or surgeries to understand how cancer cells function

Clinical trials help doctors and hospital teams understand how new drugs work and whether they are safe to give to patients. They also provide information about whether new drugs have the potential to be better than current treatments given for patients.

Clinical trials have helped improve the current standard of care and have helped patients live longer and have a better quality of life.

What Are Phases of Clinical Trials?

Any new drug goes through a number of phases before it can receive its licence, starting at the pre-clinical stage in the laboratory and going on through three more phases. Only if each phase shows promise does it go on to the next stage.

Pre-clinical trials

Researchers test a new drug in the laboratory to see how effective it may be at treating a patient's cancer. At this stage it may not be known if it is a potentially helpful drug, so patients are not involved at this stage.

Phase 1 trials

If the drug proves to be a potentially effective and beneficial drug in the laboratory and appears safe to give to patients, researchers will begin to treat a small number of cancer patients on a Phase 1 study, also known as early phase trials. These trials usually involve only one drug rather than a combination of drugs. At this stage, patients are given only a very small amount of the drug to ensure a patient is kept safe and to allow for close monitoring to see how patients tolerate the drug.

Researchers are aiming to find out the following:

- How much of the drug is safe to give to a patient?
- What are the side effects of giving the drug?
- Does the drug have any effect on the patient's cancer?

Phase 2 trials

Phase 2 trials often include more patients than a Phase 1 study. Patients will still be monitored very closely to see how the drug is working against the cancer and to continue to monitor any side effects.

Researchers are aiming to find out the following:

- What are the side effects of the drug and how they can be managed?
- What type of cancer is the drug effective for?
- What effect is the drug having against the cancer?

Phase 3 trials

Phase 3 will involve much bigger groups of patients—sometimes thousands of patients in different locations around the world. Patients will continue to be monitored closely to see what effect the drug is having against the cancer. Phase 3 trials are often comparing the current standard of treatment against the new drug.

Researchers are aiming to find out the following:

- Is the new drug as good as the current standard of care treatment?
- Is it better than the standard cancer treatment?
- Does it have fewer side effects?

What Methods Are Used In Clinical Trials?

What is a randomised trial?

In randomized trials, also known as randomised controlled trials (RCTs), a computer programme will place patients into two groups at random: one group receives the treatment being investigated, and the other group receives standard care or a placebo.

Most phase 3 trials and some phase 2 trials are randomised. By randomising patients it enables researchers to make a fair comparison of the health outcome results of the different groups.

What is a placebo?

A placebo is an inactive treatment or 'dummy drug'. It has no active ingredients in it. It looks exactly like the active medication and can be given in the same way, through a drip in the arm, or in tablet or injection form. Placebos are sometimes used within clinical trials as a way to test the effectiveness of the drug in the trial.

A secondary breast cancer patient participating in a trial will always receive the minimum standard of care treatment. It would not be ethical to give them a placebo. Placebos may be used in the later phases of a trial alongside other medications so that care for advanced breast cancer is not compromised.

What Are Benefits of Participating in Clinical Trials?

Patients have found many benefits to taking part in a trial.

- Early access to new drugs that are not yet available as part of standard of care. Having access to these new trial treatments might show greater benefit for patients than those drugs or treatments currently used in secondary breast cancer treatment.

- Close monitoring and care while on the trial. Clinical trials will usually involve very close follow up of patients and it may be that scans, blood tests and assessments of potential side effects are more frequent than standard treatment without the trial. This can be reassuring to patients since it allows any changes or symptoms to be picked up and dose adjustments made to their care quickly and effectively.

- Some trials are interested to learn how a patient feels during the treatment and how the trial drugs are affecting your daily life. This can be a great way to tell researchers, scientists and doctors the thoughts and experiences of being involved in the trial, and they can use that information to change and improve treatments in the future.

- Once all trial treatment is completed on the trial, patients still have all the usual follow up appointments with their local cancer doctor. They are always kept up to date about their progress and care while on the trial.

What's Involved in a Clinical Trial?

Every study has its own protocol. This is a very detailed, often long document that sets out how the clinical trial will be delivered and run. It explains the reasons for the trial and what happens during the trial. It includes lots of information about follow up with patients even after the trial has closed, as well as including details about who can take part and who it isn't suitable for.

All trials are managed by a team of researchers. The main researcher is usually a medical doctor that already works in the cancer hospital and is a specialist in cancer. The rest of the research team consists of other experienced doctors, nurses and coordinating staff who together manage and run the study at that hospital.

Every study is asking a particular question about the treatment that is being given within the study. Is it better than the current gold standard of care? Or is it equally as good but with fewer side effects? It's good to understand what question they are asking and how this will affect you.

Things to consider:

- What drugs are being given and how often will you get them?
- Is this a randomised trial?
- What's already known about the drugs in the trial and what are the expected side effects?
- How does this treatment differ from what you would receive if you weren't taking part in the trial?
- How will the drugs be given? In tablet form, an injection or through a drip perhaps and how often will this happen?

Clinical trials for secondary breast cancer have strict guidelines about who can and cannot take part in each trial. Each trial will be suitable for only certain breast cancer type or certain stages of their breast cancer treatment. Researchers follow these guidelines to make sure only the appropriate patients take part in a specific clinical trial. This helps to ensure a patient's safety and that the trial results are accurate. These guidelines are known as inclusion and exclusion criteria and are included in all clinical trials.

What Is Informed Consent?

As part of the clinical trial process, patients will be asked to give consent to take part in any clinical trial. This will usually involve giving written consent, although sometimes this can be done electronically.

Giving consent is also known as having informed consent. It is important that patients understand their participation in the study and what it will involve.

The consenting process starts when the doctor first discusses the trial with the patient and remains until all the treatment and follow up within the trial is completed.

You should consider the following before you can give your consent to taking part in a clinical trial:

- Are you comfortable that everything has been explained clearly to you?
- Have your questions been answered?
- Do you understand what the trial will involve? Do you feel like you can participate in the trial as the protocol requires?

Any baseline tests or treatment will not start until after the patient has given their consent to take part in the trial.

Withdrawing Consent

It's important to know that you can change your mind about taking part in the trial at any time. If you withdraw your consent to take part in the trial, you would be taken off the study. If this happened, you would return to the current standard of care treatment option. You do not have to give a reason why you wish to withdraw from the study if you don't want to.

"Vivienne was exceptional in helping me understand and navigate the clinical trial process"

Questions To Ask Before Joining A Trial

Here are some general questions to think about asking your consultant or research nurse before you take part in any clinical trial. Most of these should be answered in any discussions about the trial and should also be explained in the written participant information sheet about any clinical trial.

- What is the aim of the trial and how will it help me or others in the future?
- What types of treatment would I get in the trial and how is it given?
- How long does the treatment take to be given?
- How can I expect to feel whilst on the treatments?
- What are the benefits and risks of the trial?
- How long is the trial expected to run for?
- Will being in this trial involve a lot more tests and scans?
- Will I need to attend lots of extra hospital appointments?
- When will the results be available and will I be informed?
- Are there lots of questionnaires to fill in?
- If I have to travel outwith my local area, how will I get there regularly, especially if feeling unwell?
- Is there help available for expenses incurred for being in the trial?
- If I decide not to go into a trial, what treatments will I get instead?
- If I leave or stop the trial for any reason before it officially closes what happens and can I do that?
- Can I change my mind about being on the trial? Will it affect how I am treated by my doctors and nurses?
- Who can I talk to if I have concerns or questions about trials in general or a specific trial being considered or already taking part in?

What Is the Patient Trial Advocate (PTA) Service?

The PTA service is an advisory, informative and supportive service for patients with secondary breast cancer to find out more about clinical trials.

The PTA service is staffed by breast cancer nurses with experience in supporting patients in research settings. Anyone in the UK can use the PTA service. You can find out more about how clinical trials work and what might happen if you consider taking part in a clinical trial. The PTA nurses can also search the various databases on your behalf to see what clinical trials might be available for you as a next treatment option. The PTA service does not replace the clinical guidance and expertise of your consultant and clinical team.

Booking an appointment with the Patient Trials Advocate Team

If you are a patient with secondary breast cancer and are interested in finding out more about clinical trials or having a search done to see what trials might be available for you, you can contact the PTA team to make an appointment at a time to suit you.

You can access the booking form and appointment calendar at the Make 2nds Count website under the support section:

www.make2ndscount.co.uk/support/pta/

After you complete the booking form, you will be directed to the appointment calendar. To help the PTA support you at your appointment and to do a search of trials for you, the following information is helpful:

- Your contact details
- What type of breast cancer you have (e.g., ER+, HER2-, TNBC etc.)
- Approximate dates of diagnosis of primary and secondary breast cancer
- What types of cancer treatment you have already had

The more information you can give the better, especially if you are interested in having a search for possible trials.

One of the patient trial advocates will telephone you at the appointment time. Calls can last from 10 minutes to sometimes over an hour. The conversation will happen at your pace and will address your specific questions, concerns and requirements.

A relative or friend can do this on your behalf if they wish to find out more about clinical trials. We're happy for them to contact us using the booking form.

There's a short section on data protection and an option to give feedback at one and six months after the call. We find this helpful to guide us to direct the service to our patients' needs. Although it's brief it gives us useful information about your experience. We're also keen to see if patients do participate on a trial after using the service. Both feedback requests are done via a short, emailed questionnaire and the results anonymously reported to the PTA service for future service improvements.

Data Protection is taken very seriously at Make 2nds Count. The booking form is shared with the relevant PTA, where it is stored on an NHS database to allow them to assist in searching for a clinical trial.

In accordance with the EU & UK General Data Protection Regulations information is stored for a maximum of 12 months before being destroyed.

"Vivienne is so knowledgeable and so very supportive.

Great advice"

PTA Trial Search Process

To search for a suitable trial, we check a number of research databases that have information of trials currently running in the UK. We regularly check these databases to ensure accurate and up-to-date information is always provided. However, there are times when there are changes to a study and the databases have not been updated as quickly as we would like and so sometimes these databases do have inaccuracies.

The patient trial advocate does not have access to your medical records, so searches are based on the information you give on the booking form and during the call. A report will be sent to you via email which you can then take to your clinician to see if one of the studies identified might be suitable.

We can look for clinical trials in your local area or anywhere else across the UK, depending on how far you are prepared to travel. Ultimately you and your clinician will decide whether travelling is the best option for you at this time. Clinical trials might be focused on the following:

- Specific type of secondary breast cancer (ER+, HER2-, TNBC, etc.)
- Specific gene mutations
- Previous primary and/or secondary breast cancer treatments
- Current or former medication treatments
- Solid cancers that have spread to specific areas of the body (e.g., liver, lungs, etc.)

Trials have specific eligibility criteria to enter a trial. These are known as inclusion and exclusion criteria. Due to the inclusion and exclusion criteria, it may be that there isn't a suitable trial available for you at this time. As new treatments and trials for secondary breast cancer are being developed regularly, there may be options for you in the future.

If you wish, we can send a short letter to your clinician letting them know you've been in touch with Make 2nds Count and are keen to find out more about clinical trials. This can help to generate a positive conversation with your clinician about trials, and the letter is usually filed in your medical notes at the hospital.

You might feel that taking part in a clinical trial is not right for you at this time and you are happy to continue with the current treatment. That is absolutely fine! We are here to support you with the opportunity to know what your options are to make that decision.

There are no limits to how many times you can use the service. We are happy to do as many searches for you as you need, as your situation changes.

You can book an appointment with one of our PTA nurses by scanning the QR code below:

Lesley's Story

'I was diagnosed out of the blue with metastatic HER2+ breast cancer in March 2014. When I was told the disease wasn't curable, it felt like the ground had opened up below me. I was plunged into 6 months of grief, at the loss of all those milestones that most take for granted - children getting to high school, going to university, getting married and so on.

The cancer was in my liver, lungs and bones, and later spread to my brain. I was very unwell. Chemotherapy worked and I also had whole brain radiotherapy. However none of the targeted treatment lines that followed worked, and 18 months after being diagnosed I was told to 'get my affairs in order'.

I had a friend with blood cancer who was on a trial, flying to the Royal Marsden every month with her travel expenses paid for by the pharma company. She gave me hope that a trial could be an option for me, and so from early on I asked my oncologist about clinical trials. I would also spend many hours searching ClinicalTrials.gov, a global trials database (I wouldn't recommend it - very unpatient friendly!).

After being told I needed to get my affairs in order, we went to New York on a family holiday, thinking it would be my last. On my return my oncologist offered me another chemo, or the last slot on a phase 1 trial in Glasgow.

Very quickly I was undergoing tests and scans in Glasgow at the specialist trials unit, to check my eligibility for the trial. I stayed at a hotel in Glasgow (paid for by the pharma company) because these were quite intensive days. When I started on the trial I had 1:1 closely monitored care by the trial team, and within 2 weeks I felt better and knew the drugs were working. A scan a month later confirmed that I was having a great response to the drug. That response lasted for 7 years.

The trial couldn't have been easier -I took 6 pills every morning, and drove to the Beatson clinic every 3 weeks to see the oncologist, to get a new stock of the pills and a Herceptin injection. The pharma company even reimbursed me for my travel expenses.

Being on the trial gave me years of life I didn't expect to have. I enjoyed many more holidays with my family, and saw my children grow up. As a result I have become determined to raise awareness amongst other patients of the benefits of clinical trials.

My message to fellow patients is to raise the subject of a trial early on with your clinician, and every time you have to change treatment lines ask again about trials. You could also use Make 2nds Count's Patient Trial Advocacy (PTA) service and talk to one of the very experienced nurses there who will do a trials search for you.

I can honestly say that getting involved in a clinical trial is one of the best things I have ever done.'

Other Useful Organisations

Make 2nds Count
www.make2ndscount.co.uk

Breast Cancer Now
www.breastcancernow.org
Tel: 0808 800 6000

Cancer Research UK
www.cancerresearchuk.org/about-cancer/find-a-clinical-trial
Tel: 0808 800 40 40

My Tomorrows
www.mytomorrows.com/en/get-in-contact
Tel: 01276 543 371

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Useful Numbers & Notes

Useful Numbers & Notes

Together we can Make 2nds Count

We are here to help if you are a patient with secondary breast cancer. Please get in touch if you would like to support the vital work we do.

Find us at:

Make2ndsCount.co.uk
hello@make2ndscount.co.uk

Registered charity SC048268