TO BE PRINTED ON HOSPITAL HEADED PAPER

FAST-Forward BOOST

FAST-Forward Boost: A randomised clinical trial testing a 1-week schedule of curative simultaneous integrated boost radiotherapy against a standard 3-week schedule in patients with early breast cancer

PATIENT INFORMATION SHEET – including early side-effects sub-study

Version 2.0 Dated 18/06/2025

You are being invited to take part in a clinical trial called FAST-Forward Boost.

- FAST-Forward Boost is looking at whether we can reduce the number of radiotherapy treatments for patients with breast cancer who also need boost treatment.
- Before you decide if you would like to take part, it is important that you understand why the research is being done and what it will involve for you.
- In this information sheet you will be able to find details on why the study is being done, why you have been invited to take part and what will be involved if you do decide to take part.
- Please take the time to read the information sheet carefully. Feel free to discuss it with friends, relatives or your GP if you wish.
- Please ask your study doctor or nurse if there is anything that is not clear or if you would like more information. They can be contacted using the contact details in the 'How to contact us' section on page 2
- Your participation is entirely voluntary. If you decide not to take part this will not affect your standard of care or any future care you will get.
- If you decide to take part, you will be asked to sign a consent form.
- Even after you have signed the consent form, you can change your mind at any time and withdraw from the clinical trial. You do not have to give a reason.

This clinical trial is coordinated by
The Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU)

ICR The Institute of Cancer Research

NIHR | National Institute for Health Research

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How to contact us

If you have any questions about this trial please contact your hospital team

<local name and contact number>

PART 1

1. Why are we doing this trial?

Each year in the UK, around 37,000 patients have radiotherapy for breast cancer. Radiotherapy uses radiation to kill cancer cells. Radiotherapy is given to the breast and, if needed, to the lymph node regions in daily doses (known as "fractions"). Radiotherapy reduces the risk of cancer returning locally and reduces the risk of spread elsewhere in the body. Until recently most patients needed at least 15 daily treatments of radiotherapy. Some people also need an additional dose to the part of the breast where the cancer was. This is called a boost. The boost dose has been shown to further reduce the chance of breast cancer coming back in the breast. Young patients and those with slightly higher risk cancer are most likely to benefit from boost treatment. For patients requiring a boost, this was delivered in up to 8 extra radiation treatments to the part of the breast where the cancer was, resulting in a total of 23 days of treatment for some patients.

Following a large trial called FAST-Forward (involving over 4000 patients, and with 10 years of follow-up), many patients can now be treated in 5 treatments over one week. This is because FAST-Forward showed that delivering radiotherapy to the breast in 5 treatments is as safe and effective as delivering radiotherapy in 15 treatments. (In the 5-treatment schedule, the radiotherapy dose per day is slightly higher so that the treated area receives a biologically similar dose to 15 smaller daily treatments.) A follow-on trial has since shown that delivering radiotherapy in 5 treatments to the armpit nodes is associated with similarly low rates of side effects to delivering armpit node radiotherapy in 15 treatments.

In parallel, another large trial has tested an advanced radiotherapy technique called a "simultaneous integrated boost" (SIB), which allows us to deliver the boost dose to the part of the breast where the cancer was ***at the same time*** as the standard dose that is given to the whole breast and/or lymph nodes. This trial showed that giving a SIB within a 15-treatment course of radiotherapy to the breast (+/- lymph nodes) is as effective and safe as giving the boost dose at the end of treatment (over a total of 23 daily treatments). This means that all patients receiving radiotherapy for breast cancer with a boost can now be treated in a maximum of 15 daily treatments over 3 weeks.

The next step is to combine the 5-fraction schedule with the advanced SIB technique by comparing a 1-week (5-fraction) SIB schedule with a 3-week (15-fraction) SIB schedule. This is what FAST-Forward Boost will test.

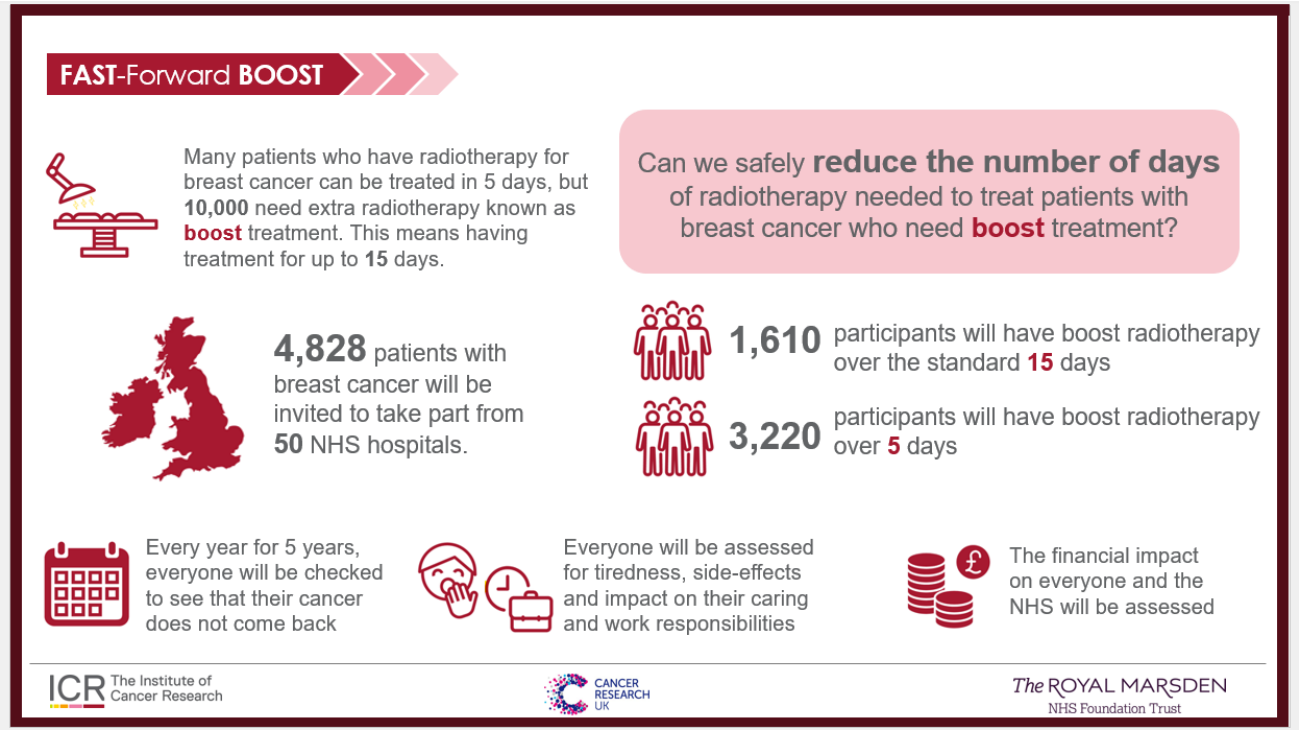
In the FAST-Forward Boost trial, we want to find out:

- **If giving a SIB within 5 daily treatments over a total of 1 week is as good at stopping cancer returning as a SIB delivered within 15 daily treatments over a total of 3 weeks.**
- **If the side-effects of treatment will be the same or less when giving the boost treatment over 5 daily treatments and whether patients recover faster.**

- **If, for patients needing radiotherapy to lymph nodes behind the breastbone (the internal mammary nodes), the side-effects of treatment will be similar when giving nodal radiotherapy over 5 daily treatments rather than 15.**
- **If giving radiotherapy over a shorter time can reduce the financial impact of treatment for the NHS and for patients.**

By comparing two different 5-treatment boost doses with the standard 15-treatment boost dose, we can also identify the 5-treatment boost dose that most closely matches the 15-treatment dose in terms of outcomes.

Over 40 NHS radiotherapy hospitals in the UK will be involved in FAST-Forward Boost, and we also hope to recruit patients in other countries. We plan to recruit 4,830 patients. We expect recruitment to continue until 2028 and everyone in the trial will be followed up for 5 years. We expect to be able to analyse the data that has been collected during the trial in 2033.



2. Why am I being asked to take part?

You are being offered the chance to take part in the FAST-Forward Boost trial because you have been diagnosed with early breast cancer and your clinical team has recommended a course of radiotherapy which includes a boost dose to where the cancer was.

3. What will happen if I decide to take part?

If you decide you would like to take part in the FAST-Forward Boost trial, you will be asked to sign a consent form. Following this we would like to record your medical history and inform your GP that you are taking part in this trial. You will be asked to complete some questionnaires about how you are feeling and to record any symptoms that you are experiencing.

You will also be asked to consider donating up to three blood samples and part of the tissue sample from your original diagnosis (already stored at your hospital). You will also be asked to consider donating other samples which have been or will be collected as part of routine care. These samples would be a gift to the FAST-Forward Boost trial and you will be asked if they can be used for future research. You can still take part in the trial if you would rather not donate any blood, tissue and/or other samples.

You will then be randomised to receive either the standard 15-fraction SIB radiotherapy treatment, or one of the two new 5-fraction SIB radiotherapy treatments (the randomisation process is described in section 5 below). Your allocated radiotherapy treatment will usually start within 4 weeks of randomisation.

During your treatment you will be assessed regularly by the research team. You will be asked to complete questionnaires about how you are feeling and to record any side-effects that you are experiencing.

After completion of your radiotherapy treatment, you will continue to be followed up by your research team for 5 years. During this time, you will also be asked to complete similar questionnaires about your health and how you are feeling. Beyond 5 years, the research team plan to continue collecting data on outcomes via NHS and national electronic health and registration data.

4. Do I have to take part?

No, it is up to you to decide whether to take part in this trial. Your participation is entirely voluntary, and you will be given sufficient time to decide if you wish to participate. The standard of care you receive will not be affected by your decision. If you do agree to participate in the trial, you are free to end your participation at any time without giving a reason.

If you decide not to take part in the FAST-Forward Boost trial, you will get the standard radiotherapy treatment used in your hospital. For many patients, particularly those requiring radiotherapy to the lymph nodes, standard radiotherapy treatment is given in 15 treatments.

What if I have private medical insurance?

If you have private medical insurance, please check with your insurance provider that your medical insurance policy will not be affected before agreeing to take part in this trial.

5. Which radiotherapy treatment will I receive?

If you decide to take part in the FAST-Forward Boost trial, you will receive either standard radiotherapy SIB treatment which is 15 daily treatments given over three weeks **or** one of the two new radiotherapy SIB treatments given as 5 daily treatments over one week. Radiotherapy doses are measured in units known as Gray (Gy).

The choice of which type of radiotherapy treatment you receive is made at random, by a computer, at the time that you enter the trial. This process is called 'randomisation'. This is the best way to make sure that the patients in each group are as similar as possible. If one group fares differently to another group, it is more likely to be because of the treatment, rather than because the patients in one group are somehow different to those in the other group.

There are three groups in FAST-Forward Boost:

- In the 'Standard care' group, patients will have standard radiotherapy SIB treatment given as 15 daily treatments over 3 weeks. The radiotherapy dose is 40 Gray to the breast (and lymph nodes if needed) and the area needing boost treatment receives 48 Gray at the same time.
- In 'Group 1', patients will have radiotherapy SIB treatment given as 5 daily treatments over 1 week. The radiotherapy dose is 26 Gray to the breast (and lymph nodes if needed) and the area needing boost treatment receives 31 Gray at the same time.
- In 'Group 2', patients will have radiotherapy SIB treatment given as 5 daily treatments over 1 week. The radiotherapy dose is 26 Gray to the breast (and lymph nodes if needed) and the area needing boost treatment receives 30 Gray at the same time.

You will have an equal chance of being in one of the three groups. Whichever group you are randomised to, everybody who takes part in the trial will receive the best possible care and regular monitoring by their clinical team. It is important that you only enter this trial if you are prepared to accept any of the treatments.

6. What happens during my radiotherapy treatment?

Before you begin any radiotherapy treatment, you will visit the radiotherapy department. A plan is made for your treatment using a Computed Tomography (CT) scan. This takes a series of images that are collated by a computer to give a detailed picture of the inside of your breast and ribcage. This helps the radiotherapy specialists see the area where your tumour was and plan your treatment. The CT scan uses x-rays at very low doses and the scan appointment will take about 30 minutes.

When you attend for your radiotherapy treatment, the radiographers will ensure that the radiotherapy is given to precisely the same region of your breast (and/or lymph nodes) by taking images. This is called image guided radiotherapy (IGRT). Each treatment session will take up to 30 minutes.

The radiotherapy and CT imaging that you will receive is part of your routine care. If you take part in this study, you will not undergo any additional exposure to radiation over and above standard practice. These procedures use ionising radiation (x-rays) to form images of your body, to ensure targeted treatment delivery and higher energy radiation provides your radiotherapy treatment. Ionising radiation can alter the way cells work, which may lead to a very small increase in the risk of developing a further cancer in the years or decades after radiotherapy, caused by the treatment itself. There is always a chance of this occurring with any radiotherapy treatment (whether this is part of a study or not).

We need to make sure that all plans are of a high quality at every radiotherapy centre. We will ask your permission to send a copy of your treatment plan and the CT planning scan to the FAST-Forward Boost Quality Assurance team where it will be stored in accordance with national guidelines to ensure confidentiality. Your details apart from trial ID will have been removed before they are forwarded to the trial quality assurance team.

If for any reason, your radiotherapy team are unable to plan your radiotherapy treatment according to the FAST-Forward Boost requirements, they will discuss this with you. In such situations it is possible that you will no longer be able to take part in FAST-Forward Boost and you will have your radiotherapy department's standard of care treatment.

Pregnancy during treatment

Radiotherapy can be harmful to a developing baby. You should not become pregnant before or during treatment. Appropriate contraception should be used. Your clinical team can advise you on appropriate methods of contraception. If you think you may be pregnant, you must tell the nurses, radiographers or your hospital doctor before you have any treatment.

Please tell your healthcare professional what medication/treatment you are on so they can advise if any changes need to be made whilst you are having radiotherapy treatment, as some medications/treatment shouldn't be given during radiotherapy and immediately after it.

7. Does the treatment have any side-effects?

All radiotherapy treatments have potential side-effects, whether they are given as part of a trial or not. The risks of these side-effects in your case will have been discussed with you as part of your general consent to radiotherapy before being offered this trial. The risks of radiotherapy side-effects are expected to be very similar whether you are treated in the trial or not.

Short-term side-effects can include skin changes and tiredness. On rare occasions, patients who also need treatment to their lymph nodes behind the breastbone may have some discomfort when swallowing, but this is temporary. Inflammation of the lungs (pneumonitis) is a rare side-effect which causes a cough, breathlessness, and tiredness. These side-effects are all treatable and are likely to resolve completely.

Late radiotherapy side-effects (occurring after at least 6 months) include changes in how the breast looks, such as breast shrinkage and hardening (which are usually minimal). For patients having radiotherapy to lymph nodes there are low chances that radiotherapy may increase the risk of developing arm swelling, known as lymphoedema. Major side-effects such as heart disease and

second cancer are rare. It is nearly always possible to protect your heart from the radiotherapy. This can be done by either using shielding (in the head of the radiotherapy machine) and/or by getting you to take a breath in and hold it during your radiotherapy treatment.

8. What other trial specific assessments will be performed?

Medical assessments

Before you start radiotherapy treatment your medical team will record the following:

- Medical history
- Weight and height
- Breast assessment
- Optional blood sample

At 1, 3, 5 and 7 weeks after the start of your radiotherapy treatment, you will be seen by your clinical team to assess any side-effects that you may be experiencing.

3 months after the start of your radiotherapy treatment, you will have an appointment with a member of your clinical team (in clinic or by remote consultation) to check any side-effects that you may be experiencing.

1 year, 3 years and 5 years after the start of your radiotherapy treatment, you will be seen by your clinical team to assess any long-term effects that you may be experiencing.

From 5 years researchers at the Clinical Trials & Statistics Unit at the Institute of Cancer Research (ICR-CTSU) will find out how you are getting on by using your NHS national records.

Assessments collected in Questionnaire Booklets

Patients who have experienced boost radiotherapy treatment for breast cancer have helped us to design FAST-Forward Boost. In addition to collecting medical information, they have told us that it is important to collect information about your experience of any side-effects, including tiredness, and how these may impact on your quality of life as well as the costs associated with attending for radiotherapy treatment. We would also be interested to know how you use other healthcare resources.

To collect this information, we will ask you to complete some standard questionnaires. Some of the questions may seem a bit repetitive and we would ask that you to please bear with us and answer them as best as you can. There are no ‘right’ or ‘wrong’ answers. Some questions may be sensitive for participants. All questions are optional. If you do not wish to complete any questions in the questionnaire, there is no pressure to do so. When the trial opens you will be asked whether you would like to complete these questions on paper or electronically, although you can change your preferences at any point throughout the trial. We will collect both your home address and email address details to allow both options. When the trial first opens, you may need to complete these on paper regardless of your preference.

Early side-effects sub-study

In the early part of FAST-Forward Boost, we are collecting more detailed information about side effects during and immediately after radiotherapy. This is a necessary precaution in any radiotherapy trial testing a new schedule and is called the 'early side-effects sub-study'.

This sub-study is to closely monitor participants in FAST-Forward Boost to demonstrate that there is no increased risk of early side-effects for those having the new 5-day SIB treatment in Group 1 and 2. Previous research studies in similar settings suggest that is more likely that those in Groups 1 and 2 will experience fewer skin side effects than those in the Standard Care Group.

You will be asked to record information about any changes to your breast and skin where you have had radiotherapy treatment, and any changes that affect your swallowing. You will be asked to record this information in your questionnaire booklet before you start radiotherapy treatment, and from the start of radiotherapy weekly for 7 weeks and then at 3 months.

Pre-treatment questionnaire booklet

The first questionnaire booklet will be given to you to complete in clinic, after you have consented to the trial. You will be asked to complete the booklet before you know which of the treatment groups you have been allocated (to understand your situation at the outset).

You will also be asked to answer some questions about yourself (such as your ethnicity, and caring responsibilities) so that we understand more about those taking part and include participants from all backgrounds and life experience in our trials.

A member of your medical team will explain the booklet and answer any questions that you have. The questionnaire booklet will take around 10-15 minutes to complete.

Booklet with weekly questionnaires (weeks 1-7)

You will be given the second questionnaire booklet in clinic before you start radiotherapy treatment. At the end of each week during and after your radiotherapy treatment, we would like you to use these questionnaires at home to record information about any changes to your breast and skin, any changes that affect your swallowing, your tiredness levels, your quality of life and the costs associated with attending for treatment.

The questionnaires are all part of the same booklet and will take around 5 minutes to complete. There will be a pre-paid envelope for you to return the completed booklet at the end of week 7 to researchers at the ICR-CTSU where the trial is being coordinated.

Follow-up questionnaire booklets (3 months, Year 1, 2, 3, 4 and 5)

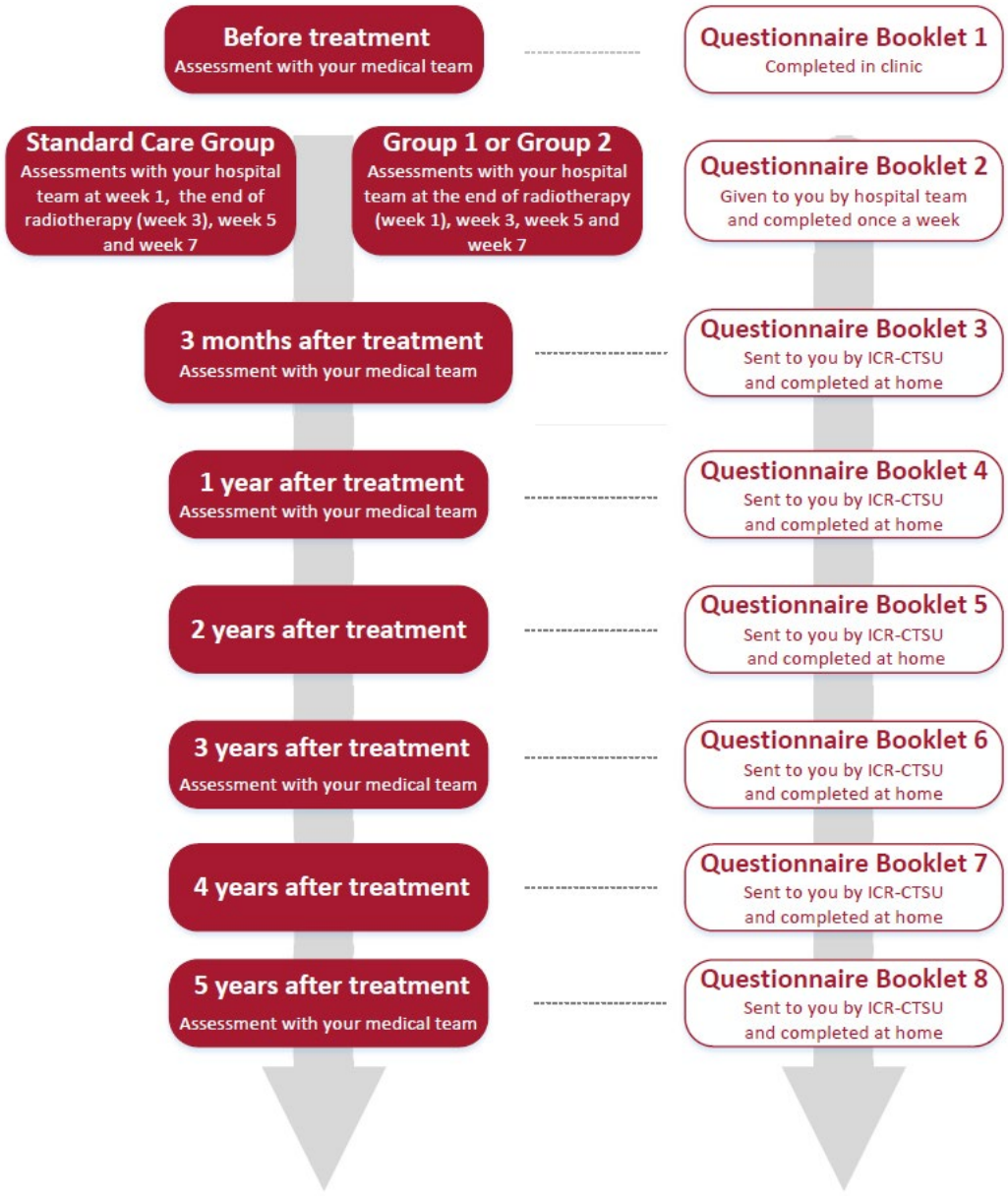
You will be asked to complete questionnaire booklets at 3 months, 1 year, 2 years, 3 years, 4 years and 5 years after radiotherapy treatment to assess any late side-effects, your quality of life, and information about how you use healthcare resources, such as hospital or GP visits. Each booklet should take about 10 minutes to complete.

The paper booklets will be sent to you at your home address by the researchers at the ICR-CTSU. To do this, we need to collect details of your home address. There will always be a pre-paid envelope for you to return the booklet to the ICR-CTSU. You will be sent reminders about the questionnaires.

If you prefer electronic completion (when available), you will receive email notifications when questionnaires need to be completed at the above timepoints (pre treatment, weeks 1-7, 3 months, years 1-5).

The information you provide in the questionnaires will be kept strictly confidential. Your medical team will not be informed of your answers, unless your answers tell us that you are anxious and/or depressed and may need help. In these cases, we will tell your hospital medical team.

Summary of your Research Assessments and Questionnaire Booklets



9. Will I be asked to do anything else?

We know that blood and tumour samples provide much useful information on improving trial treatment, including helping understand why some patients develop radiotherapy side effects and why sometimes the cancer comes back. Therefore, we are asking whether you would be willing to donate some blood for the trial. We will also ask you whether you would be willing to gift the tumour tissue and other samples that are taken as part of your usual care, so we can learn as much as possible from everyone who takes part in the FAST-Forward Boost Trial.

All the donations described below are an optional part of FAST-Forward Boost, and you do not have to donate samples to take part in the trial.

Blood sample donation

We are asking you to donate 4 teaspoons of blood ideally before you start radiotherapy. Additionally, if you agree, we would like you to donate another 4 teaspoons of blood at the end of radiotherapy and again 2 weeks after. If you do consent to these blood samples for the FAST-Forward Boost Trial, we will also ask you if you consent for them to be used for future research.

Tissue sample donation

When you had your operation, the breast cancer was removed and stored in your hospital's pathology laboratory. As part of FAST-Forward Boost, we are asking participants if they would like to consent to donating some of this stored tissue for the FAST-Forward Boost trial and for future research. Sometimes the breast cancer can return in the same breast, or another cancer can develop in your opposite breast. Both situations are unlikely to happen. If, however, you did develop breast cancer again, we would also like to ask your permission to collect a small part of tumour tissue taken from any routine biopsies or surgeries performed as part of your standard care in order to help us better understand why cancer occasionally comes back. This request does not involve taking any new samples, simply your permission to access the samples that have already been taken.

If you develop another breast cancer, it is usual to have an imaging scan of the body as part of standard care. We will also ask you to consent to use of this imaging scan too as it gives important information about the position of the breast cancer.

Other sample donation

You will also be asked to consider donating other samples (such as and not limited to blood, urine, scans) which have been or will be collected as part of routine care for use in the FAST-Forward Boost trial and for future research into cancer. This request does not involve taking any new samples, simply your permission to access the samples that are collected as part of routine care.

What will happen to the samples I donate?

Your samples will be sent to a specialist research laboratory and will be identified by your Trial ID, initials and month and year of birth only. Once at the research laboratory, they will be processed and

given a unique identification number and will be stored securely and in strict accordance with national guidelines.

The samples you donate may be used in the future for analysis that could include genetic analysis. Cancer can be caused by changes in our genes that occur after we are born. We can test for this type of change using the genetic material from cancer cells. This type of testing may be done on your samples if you agree to allow your samples to be used for future research.

We would also like to be able to make your samples and any information necessary for their analysis, including imaging scans performed if the cancer was to come back as part of standard care, available to other researchers for future medical research. This may involve researchers and organisations outside of the UK and European Economic Area (EEA). This could also include the genetic testing described above. It is possible that the future research will be carried out internationally.

Any future research using your tissue must be approved by an independent Research Ethics Committee before it is allowed to go ahead. Any tissues samples and information relating to them transferred to third parties will not contain your personal information, so researchers will not be able to identify you from the information provided.

It will not be possible to release the results of these future tests to you or your research team and they will not form part of your medical records.

10. The advantages and disadvantages of taking part in the trial?

What are the possible advantages of taking part?

Participants allocated to either Group 1 or Group 2 will have their radiotherapy in 5 treatments. This may reduce short-term side-effects such as skin changes and tiredness. It will save you time travelling and may reduce the costs connected with treatment (such as parking charges, time away from work, and caring responsibilities). The dose of radiotherapy to your heart and lungs may also be lower which may help to reduce the risk of any longer-term side-effects. All participants who take part in the trial will be followed up closely by their research team for 5 years.

What are the possible disadvantages and risks of taking part?

Large trials have already shown that radiotherapy doses in 5 daily treatments to the whole breast is as effective at preventing cancer from returning as 15 or more daily treatments. These trials have also shown that radiotherapy treatment in 5 fractions is safe and has no increased risk of side effects compared to the 15-treatment course. A follow-on sub-study in patients needing armpit node radiotherapy has also shown that side-effect rates are as low following 5 treatment as for patients treated with 15 treatments. Another large trial has shown that giving the boost simultaneously with 15 radiotherapy treatments to breast and/or nodes (as required) is as effective and safe as giving the boost at the end of treatment. The design of FAST-Forward Boost therefore builds on decades of high-quality clinical research in radiotherapy for breast cancer. Careful analysis of this research has been made to ensure that giving the boost radiotherapy dose within 5 treatments for the breast and/or nodes is as effective. There is a small chance that giving a boost dose in 5 treatments may not be as effective as standard treatment, but this is highly unlikely to be

the case. There is also a small possibility that giving the boost dose in five treatments instead of 15 treatments may slightly increase the risk of longer-term breast changes such as hardness in the boost area, but again, differences in these side-effects are likely to be small. There should be no increased risk of longer-term side effects such as heart disease or second cancers by giving the boost dose in 5 treatments.

This trial will be the first to evaluate the use of 5 treatments in patients needing radiotherapy to the lymph nodes behind the breastbone (the internal mammary chain). Based on the previous trial data, the chance of the cancer coming back is expected to be the same for both the 5 treatments and the 15 treatments. Given that radiotherapy doses to lungs and heart are lower with 5 treatments than with 15 treatments, the use of 5 treatments in this setting is not expected to increase the risks of lung or heart side-effects.

What happens if something goes wrong?

It is unlikely that anything will go wrong with your treatment or care, but if you have any complaints about the way that you have been treated during the course of the trial, you are free to use the usual NHS complaints procedure. Your hospital will be able to advise you how to proceed with this. There are more details about this in Part 2.

Will I be paid for taking part in this trial?

No. Neither you nor your doctor will be paid for taking part in the FAST-Forward Boost trial.

11.What happens if I don't want to carry on with the trial?

Your participation is entirely voluntary. If you agree to take part and then change your mind later, you can withdraw from the trial or change your level of participation, for example by stopping trial specific hospital visits, at any time without giving a reason. You can withdraw consent for your samples to be used for future research but still continue in the study and that you can still withdraw consent for your samples to be stored future research after the study has completed. If you withdraw from the trial, it will not affect the standard of care you receive. Your doctor will discuss alternative treatment with you and offer you the most suitable treatment available.

If you were to change your participation, we would like to continue to collect information on your progress that is routinely recorded in your medical records. This is so that the overall quality of the trial is not impaired, and enough information is collected to answer the main aim of the trial.

If you decide you want to stop participation and do not want any more information to be sent to the ICR-CTSU, trial data collected before your decision will still be processed along with other data collected as part of the clinical trial. However, no new data will be added to the trial database, and you may request that all retained identifiable samples are destroyed to prevent future analysis.

However, if you were to withdraw, we would like your permission to keep the information and samples we have already collected from you and to continue to collect information on your progress that is routinely recorded in your medical records.

Should you withdraw from the trial before your first radiotherapy treatment, you will receive the standard treatment given in your hospital. It may take up to a week to replan your treatment. If you wish to withdraw from the trial during your treatment, your medical team will discuss with you whether you wish to continue with the planned trial treatment or switch to the standard treatment. If you choose standard treatment, there may be a break in treatment whilst a new radiotherapy plan is prepared for you. It is important therefore that you are happy to be in the trial and receive any of the allocated treatments. If you are concerned about any aspect of the trial, please discuss your concerns with your healthcare professional team.

This completes PART 1 of the information sheet.

If the information given in Part 1 of this information sheet has interested you and you are considering participation in the FAST-Forward Boost clinical trial, please read the additional information in Part 2 before deciding.

PART 2

1. Who is organising and funding the research?

The Chief Investigator of the trial is Dr Anna Kirby who is based at The Royal Marsden NHS Foundation Trust. FAST-Forward Boost is being carried out by a network of healthcare professionals across at least 40 NHS hospitals in the UK. The trial was co-designed in partnership with patients and is sponsored and coordinated by The Institute of Cancer Research (ICR). The research is approved and funded through the National Institute for Health and Care Research Health Technology Assessment (HTA) Programme. Your trial doctor will not receive any payments for including you in this research trial.

2. Confidentiality

How will we use information about you?

We will need to use information from you, from your medical records, your GP for this research project.

This information will include your:

- Full name
- Date of birth
- Home address
- Email address
- GP details
- NHS number or Community Health Index
- Hospital number

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The Institute of Cancer Research (ICR) is the sponsor of this research and is responsible for looking after your information. Our legal reason for using your information is to carry out scientific research which is in the public's interest. We will share your information related to this research project with the following types of organisations:

- research institutions including universities, hospitals and commercial laboratories involved in research into cancer and its treatment, where this sharing has been approved by the sponsor

We will keep all information about you safe and secure by:

- storing all your information and samples securely and in strict confidence.
- using the minimum personally-identifiable information possible.
- limiting access to your information to only those who need to use it for research or those who need to check that the research is done properly, and regularly reviewing who has access to your information.
- using strong encryption anytime we need to share your information.

International transfers

We may share data about you outside the UK for research related purposes to understand breast cancer and its treatment. If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- research institutions including universities, hospitals and commercial laboratories involved in research into cancer and its treatment, where this sharing has been approved by the sponsor

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- some of the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we

legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/report-a-breach

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 20 years from the end of study. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records / your hospital / your GP. If you do not want this to happen, tell us and we will stop.
- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information, [including the specific mechanism used by us when transferring your personal data out of the UK].

- our leaflet: www.hra.nhs.uk/patientdataandresearch
- our privacy notice on our website: www.icr.ac.uk/legal/privacy/research-privacy-notice
- by sending an email to our Data Protection Officer: dataprotectionofficer@icr.ac.uk,
- by asking one of the research team, or
- by ringing our Data Protection Officer on 0203 437 7327.

3. What if something goes wrong

Every care will be taken during the course of this clinical trial to ensure you receive appropriate care and treatment. If you are not happy with the general care and treatment you receive, please speak first to your doctor, who will try to resolve the problem. If you are still unhappy and wish to

complain formally about the care and treatment received during the trial, you may do so under the standard NHS complaints procedure, which is available to you at your doctor's hospital.

[**Sites in England**] Concerns can also be raised by talking to your local Patient Advice and Liaison Service (PALS). You can contact the PALS team at [*insert Trust name*] on [*insert relevant contact details*].

[**Sites in Scotland**] Concerns can also be raised by talking to the Patient Advice and Support Service (PASS). You can contact PASS via the National Citizens Advice Bureau on 0808800 9060 or through your local Citizens Advice Bureau (www.cas.org.uk/patientadvice).

[**Sites in Wales**] Concerns can also be raised by talking [insert complaints/patient support and advisory service team as applicable] at [Trust/Health Board name] on [insert relevant contact details].

[**Sites in Northern Ireland**] Concerns can also be raised by talking to the [Insert Trust name] complaints department on [insert relevant contact details.]

You will be closely monitored both during and after treatment and any side-effects will be treated as appropriate. If you suffer any side-effects or injury, please notify your doctor immediately so you can obtain appropriate medical attention.

In the unlikely event that you are injured by taking part, compensation may be available.

If you are harmed due to the negligence of someone treating you, then you may have grounds for legal action, but you might have to pay for it. NHS Trusts are responsible for clinical negligence and other negligent harm to individuals that are under their care and covered under the NHS Indemnity Scheme.

If you suffer adverse side-effects of the trial treatment or harm caused by procedures, you have undergone specifically for the trial you may be able to claim compensation from The Institute of Cancer Research as sponsor of the FAST-Forward Boost trial. In deciding the level of compensation to be awarded, consideration will be given to the likelihood of side-effects and any warnings that were given. The Institute of Cancer Research has no-fault compensation for human clinical trials insurance cover.

4. What if relevant information becomes available?

Sometimes we get new information about the treatment being studied, which may affect your willingness to continue in the trial. If this happens, your doctor or healthcare professional will tell you in a timely manner and discuss whether you should continue in the trial. If you decide to continue in the trial, you may be asked to sign an updated informed consent form. If you decide to withdraw from the trial, your doctor will make arrangements for your future care.

If the trial is stopped for any other reason, we will tell you and arrange your continuing care.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the trial, we will keep the information that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information as possible.

5. What will happen to the results of the clinical trial?

Independent experts will review the progress of the research, and the results will be published in a scientific journal as soon as they are ready. The results will help to decide how to treat breast cancer in the future. The results from this trial may also contribute to reviews of worldwide evidence about this type of cancer and its treatment. You will not be identified in any report or publication relating to this research.

We will also write-up the results in non-medical terms once they are available. These will be sent to your hospital. Your specialist will inform you that they are available and ask if you would like a copy. You will also be able to access this on the FAST-Forward Boost trial website.

6. Who has reviewed the trial?

To protect your interests, all research in the NHS is looked at by an independent group, called a Research Ethics Committee. This trial has been reviewed and given favourable opinion by the London South East Research Ethics Committee.

This trial has also been reviewed and approved by the Committee for Clinical Research (CCR) which is a joint committee between The Royal Marsden NHS Foundation Trust and the Institute of Cancer Research, and which oversees all clinical research sponsored by these organisations to ensure that the research is high quality.

How have patients and the public been involved in the setting up of this trial?

A diverse group of over 40 patients with experience of radiotherapy for breast cancer from across the UK have helped us to design this trial. These patients told us that having radiotherapy treatment over a shorter time is important, as long as it does not change the risk of cancer returning. They asked us to collect information about tiredness and the effects of treatment on work and care responsibilities. Patients with experience of breast cancer have also helped to develop this patient information sheet.

7. What do I have to do now?

You will be given some time to think about the trial and make your decision whether you would like to take part or not. You may wish to discuss it with your family, friends or GP. If you decide you

would like to take part in the trial, you will be asked to sign the consent form. Please keep this information sheet and a copy of the signed consent form. If, at any time, you have any questions about the trial you should contact your doctor using the contact details on page 2.

8. Further information

Who else can I contact for further information?

You have the right to ask questions about this trial at any time and are encouraged to do so. You can call your doctor / nurse if you:

- Feel that you are developing any unexpected side effects.
- Believe you have been injured as a result of receiving the trial treatment or,
- Have any questions about this trial or your participation in it.

Breast Cancer Now is a registered charity providing information and support for patients with breast cancer and their families. You can contact one of their Breast Cancer Nurses on the freephone Helpline: 0808 800 6000 Monday to Friday 9:00am to 4:00pm and Saturday 09:00am to 1:00pm. In addition you can email the Breast Cancer Now Specialist Nurses or ask anonymous questions through the Ask the Nurses Board. You can find out more here: https://breastcancernow.org/information-support/support-you/contact-our-nurses

Macmillan Cancer Support is a registered charity providing information, emotional support and publications about all aspects of cancer for cancer patients and their families. You can contact one of their Cancer Information Nurse Specialists on the **Macmillan Support Line**: Freephone 0808 808 00 00 Monday to Friday 9:00am to 8:00pm. In addition to their nurses, the Macmillan Support Line also has other specialist teams that can provide advice and information relating to welfare benefits, financial issues and everyday practical concerns. You can find out more here: https://www.macmillan.org.uk/cancer-information-and-support/get-help

You can learn more about clinical trials on the **Cancer Research UK** and **Be Part of Research** websites:

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial

https://bepartofresearch.nihr.ac.uk/

Thank you for your time and interest in our research.