PRIMETIME Patient Newsletter June 2022

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## PRIMETIME UPDATE

Some time ago you agreed to take part in a clinical trial called PRIMETIME. We wanted to take this opportunity to thank you and to update you on how the trial is progressing.

PRIMETIME is a research study designed to find out whether we can identify patients with a very low risk of cancer recurrence, using a laboratory research test called Ki67 and a research calculation called IHC4+C, in order to give those patients the option not to undergo radiotherapy.

A total of 3119 people entered the study which took place in 64 hospitals across the UK. Recruitment to the trial started in May 2017 and ended on 31st March 2022. Completion of recruitment was a little later than expected due to a temporary suspension of recruitment during the first wave of the Covid-19 pandemic.

You may be interested to know that 1623 patients who were identified with a very low risk of their cancer coming back, went on to choose not to undergo radiotherapy.

### What happens next?

The questions to be answered in PRIMETIME mean that we need to follow up all participants for at least 5 years. We are asking you to continue attending clinic visits and mammogram tests as normal so that hospitals can provide us with accurate information. Patients who chose not to receive radiotherapy will be asked to undergo annual mammograms for an additional 5 years. We thank you for your continuing participation.

### Are there any results yet?

Before any results from clinical trials like PRIMETIME can be made public, a group of independent experts look at the information we have collected to make sure the results are reliable. This is important because these results may affect the treatment of patients with breast cancer in the future. However, as we need to make sure that we have sufficient follow-up information on all patients who entered the study before we publish the results, we anticipate that it will be early 2027 before a summary is available.

### Information Giving Study

809 patients who were approached about PRIMETIME were also offered the opportunity to view a video explaining the study, alongside reading the Patient Information Sheet. Of these, 521 completed questionnaires about the usefulness of these videos when making the decision whether or not to participate in the PRIMETIME study. These questionnaires indicated that most patients did not have difficulty making a decision about whether or not to participate in the PRIMETIME study, and so it was concluded that the information given to patients, whether on film or in writing was very clear. Thank you to everyone who participated in the Information Giving Study.

### Tissue Samples

All patients who took part in the PRIMETIME study had a sample of tissue from their diagnostic tests sent to our central research laboratory and were asked if any tissue left over could be stored for future research. These samples are currently being stored until requested for use in an ethically approved research study in the future.

### Further information

If you would like any further information about the PRIMETIME Trial or any other aspect of your treatment, please ask your clinic nurse or hospital doctor.

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