



Patient Summary

Tamoxifen is a drug that reduces the chance that breast cancer will return after breast cancer surgery. While there are newer drugs that may be even better than tamoxifen, they are not suitable for everyone and can have extra side effects. Tamoxifen is therefore still in widespread use and is saving thousands of lives world-wide. The aTTom trial has shown that taking tamoxifen for 10 years is more effective than taking tamoxifen for 5 years. Many women are now being advised to take tamoxifen for 10 years. Tamoxifen can often lead to side effects such as hot flushes. Putting up with these for 10 years can be quite a burden for some patients. Rare but serious side effects from tamoxifen include an increased risk of endometrial cancer (cancer of the womb lining).

The aTTom trial has been changed to aTTom-Extended. An important part of aTTom-Extended Study involves collecting longer term follow up data on patients in the aTTom trial.

We need to continue to collect information about women who are taking part in aTTom, but most patients in aTTom have now been discharged from hospital follow up. We are getting important information about what has happened to women in the aTTom study by continuing to collect information available from the National Health Service records about causes of death and any new cancers. This approach is not new, we have been doing this ever since the trial started, but now we will not be asking hospitals and GPs for updates but only collect this information through national health registry data (such as the Cancer Registries, or the Office of National Statistics for English and Welsh patients which is accessed via the NHS Digital Data Access Request Service, or the National Records of Scotland (NRS) for Scottish patients). This longer follow-up is important to assess the benefits of extended tamoxifen treatment and to monitor safety to ensure that the full impact of taking tamoxifen treatment is fully understood.

In order to do this, we provided your details (e.g. name, date of birth, NHS number) to the Office of National Statistics and subsequently to NHS Digital if you live in England or Wales, or alternatively to National Records of Scotland if you live in Scotland. This will allow them to correctly match the health service record data to the correct aTTom study patient. NHS Digital and National Records of Scotland have secure systems in place for protecting and transferring data and provide the aTTom-Extended team with information on new cancers, date and cause of death.

The aTTom-Extended Study is being conducted by the Cancer Research UK Clinical Trials Unit (aTTom-Extended Study Office) and the Birmingham Clinical Trials Unit at the University of Birmingham with assistance from statisticians from the University of Oxford who will help in the analysis of the aTTom data.

Another important part of aTTom-Extended involves collecting tumour samples.

Doctors and scientists are trying to develop tests to help decide if prolonged use of tamoxifen is really needed. A new test with the potential to help doctors and women decide if they really need more than 5 years of tamoxifen has been discovered but it needs further investigation to determine how well the test will perform. These tests are carried out on a sample of cancer tissue that was removed at surgery. In collaboration with colleagues in the USA and Canada we will test the samples from patients in the study to see if the new test really can help us in the future work out who does and does not need to take tamoxifen for more than 5 years.

If you are an aTTom participant and do NOT want us to use your data or cancer sample for research within aTTom-Extended contact the Study Office using the contact details on the next page. We will ask for some information about you so we can identify you in our trial records. If you decide not to take part you do not have to provide a reason but it would be helpful to know why you don't want us to use your data or tissue.

If you would like more information about this research, please contact the aTTom-Extended Study Office and we will answer any questions you may have.

Please note that the trials team cannot give individual's clinical advice. Patients and their families should contact their treating physician to discuss their clinical care.



More information about aTTom

Patients who took part in the aTTom Clinical Trial and would like further information are advised to visit the Cancer Help website see the link below.

[CancerHelp](#) (Cancer Research UK)

aTTom-Extended Study Office Contact Details:

Phone: 0121 414 9021

Email: aTTom-Extended@trials.bham.ac.uk

or write to:

aTTom-Extended Study Office, Cancer Research UK Clinical Trials Unit (CRCTU), Institute of Cancer and Genomic, Sciences College of Medical and Dental Sciences University of Birmingham, Edgbaston, Birmingham. B15 2TT

Data Protection Information

Who is the Data Controller?

The University of Birmingham, Edgbaston, Birmingham B15 2TT is the data controller for the personal data that we process in relation to you for the aTTom-Extended Study.

What data are we processing and for what purpose will we use it?

We will collect and process your personal data to conduct the aTTom-Extended Study, as explained above and in the aTTom Patient Information Sheet which you will have been given when you first entered the aTTom trial.

What is our legal basis for processing your data?

The legal justification we have under data protection law for processing your personal data is that it is necessary for our research, which is a task we carry out in the public interest. These data will not be used to make decisions about you.

Who will my personal data be shared with?

As described above your name, date of birth, and NHS/CHI number will be shared with Office of National Statistics and NHS Digital if you live in England or Wales, or alternatively to National Records of Scotland if you live in Scotland.

Healthcare data about you may also be shared with the lead trial statistician at the University of Oxford. It will not be possible to directly identify you from this information.

Your full name, date of birth, hospital number and date of surgery will be provided to your hospital to help them identify the cancer tissue that was removed at your original surgery. The cancer samples which will include the pathology number will then be sent to the Biomarkers and Companion Diagnostics, Edinburgh Cancer Research Centre, University of Edinburgh.

We make sure we have appropriate contracts in place with these organisations to protect and safeguard your data.

The aTTom-Extended Study Office will not share information which could identify you with anyone else.



How will my personal data be kept secure?

The University takes great care to ensure that personal data is handled, stored and disposed of confidentially and securely. Our staff receive regular data protection training, and the University has put in place organisational and technical measures so that personal data is processed in accordance with the data protection principles set out in data protection law.

The University has an Information Security Management System based on ISO27001 with a range of controls covering the protection of personal information. Annual security awareness training is mandatory for staff and the University is accredited under the NHS Information Governance Toolkit.

In relation to the aTTom-Extended Study access to your data is restricted to the named staff working on the project.

How long will my personal data be kept?

Your data will be retained for 10 years after the completion of the study final report. In exceptional circumstances it may be kept for longer if there is a justifiable reason. If you withdraw from the study, we will keep the information we have already obtained but, to safeguard your rights, we will use the minimum personally-identifiable information possible.

Your rights in relation to your data

You may have the following rights in respect of your personal data:

- The right to access to your data (often referred to as a Subject Access Request).
- The right to rectification of inaccuracies in your data.
- The right to erasure of your data (in certain circumstances).
- The right to restrict processing of your data (in certain circumstances).
- The right to object to the processing of your data (in certain circumstances).
- The right to ask for your personal data to be transferred electronically to a third party.

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

If you would like more information on your rights, would like to exercise any right or have any queries relating to our processing of your personal data, please contact:

The Information Compliance Manager, Legal Services, The University of Birmingham, Edgbaston, Birmingham. B15 2TT. Email: dataprotection@contacts.bham.ac.uk Telephone: +44 (0)121 414 3916

If you wish to make a complaint about how your data is being or has been processed, please contact our Data Protection Officer: Mrs Carolyn Pike, OBE, The Data Protection Officer, Legal Services, The University of Birmingham, Edgbaston, Birmingham. B15 2TT. Email: dataprotection@contacts.bham.ac.uk Telephone: +44 (0)121 414 3916

You also have a right to complain to the Information Commissioner's Office (ICO) about the way in which we process your personal data. You can make a complaint using the ICO's website.

More information about how we use your data can be found in the CRCTU Privacy Notice see <https://www.birmingham.ac.uk/crctu>.