Long-term Anastrozole versus Tamoxifen Treatment Effects

LATTE NEWSLETTER

The end of ATAC and beginning of LATTE

By Professor John Forbes, Chair of the ATAC SC

As you are no doubt aware, the final database lock for the ATAC Trial is taking place in early 2009. The ATAC Steering Committee would like to join AstraZeneca and Omnicare in urging you to provide the required data in a timely manner. We all want the final analysis of this trial to be as robust and complete as those that went before it.

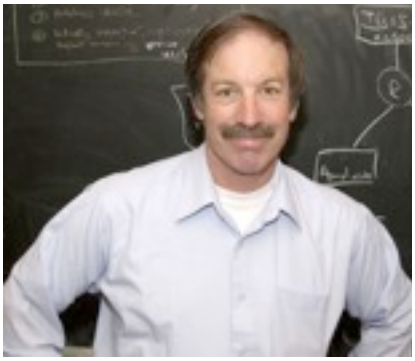
The Steering Committee has been concerned for some time that the end of ATAC does not mean we lose this unique opportunity to gather data beyond 10 years. I am therefore very pleased that, after considerable effort, financial support has been secured from Cancer Research UK and AstraZeneca for LATTE, which aims to collect key long term efficacy and safety data from women who participated in the ATAC Trial. Professor Jack Cuzick, the PI of this study, is to be congratulated for his work in reaching this goal. A protocol has been approved by the UK Research Ethics Committee, and this (and other documents) will be sent to you soon. I strongly encourage your participation.

Reaching the milestone of ten years of follow-up in ATAC is by any standards a remarkable achievement for randomised clinical trial. Apart from the scientific and medical benefits, it demonstrates that international co-operation can truly lead to great things. On behalf of the ATAC Steering Committee, I would like to thank you all for your persistence and dedication, and thank you in advance for your help with LATTE.

The LATTE Study

Long term Anastrozole versus Tamoxifen Treatment Effects

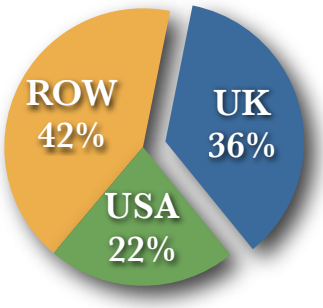
By Professor Jack Cuzick



Breast cancer survival has been improving for the past 20 years and is increasingly becoming a "survivable" disease which indicates that a risk- benefit analysis of treatment requires a careful evaluation of long term effects. Good information is available about long term survival through the efforts of the Early Breast Cancer Trialists' Collaborative Group based in Oxford, but these data are based on women diagnosed and treated 10 to 20 years ago.

The ATAC trial is the vanguard breast cancer trial for the use of AIs in the adjuvant setting, with a median follow-up of 100 months, and has already produced practice changing data for post-menopausal women with hormone sensitive breast cancer. For the first time, we have an opportunity on the long-term efficacy and safety of an aromatase inhibitor. The last patients will be attending their final follow-up for the ATAC trial in March 2009 which highlights the need to address these long-term questions now with the LATTE study.

ATAC Monotherapy Patients



This research will aim to provide additional efficacy data; time to recurrence of breast cancer in the post 10 year period and death after recurrence, as well as additional safety data; other primary cancers, serious fractures and cardiovascular events.

"Support within the UK, as the largest single contributor of patients to the ATAC trial, will prove essential for the success of the LATTE trial."

Jack Cuzick

We intend to keep the data collected in LATTE unblinded as much as possible throughout the duration of the study and therefore would like to remind all sites of the importance to the integrity of the data that codebreaks should be kept to a minimum.

As the Independent Statistician for this study we are in an ideal position to manage a system of collection of follow-up data through LATTE.

Support within the UK, as the largest single contributor of patients to the ATAC trial, will prove essential for the success of LATTE. I look forward to working with you on this important study.

NCRN National Cancer Research Network

The LATTE study is being funded by Cancer Research UK and has been added to the NCRN portfolio.

As such David Cameron, NCRN Director, has confirmed that patient follow up will count towards your NCRN activities. Negotiations are underway to determine if it will also count towards treatment RCTs figures as well.

If needed, support for this activity should be available from your comprehensive treatment network.

"Cancer Research UK is pleased to be supporting the long term follow-up of this important, practice-changing study. The information collected will be valuable in helping women make choices about hormone therapies."

Dr Julie Hearn, Head of Clinical Trials, Cancer Research

CANCER RESEARCH UK

LATTE Study Coordination

Introduction to the team

The LATTE study will be coordinated by the LATTE Operations Group – a joint collaboration between the Clinical Trials Group (CTG), UCL Medical School and the Cancer Prevention Trials Unit (CPTU), Queen Mary University of London (QMUL).

Laura White, CPTU QMUL

It is really exciting to be given the opportunity to take on the LATTE study. Having already had experience in breast cancer clinical trials through working on the International Breast Intervention Study II (IBIS – II) I am of course well aware of the pioneering results the ATAC study has so far produced and therefore the great importance to continue to follow-up these patients. As part of the LATTE Operations Group I will primarily be responsible for coordinating the UK sites. In order to meet recruitment targets and to ensure the smooth running of all LATTE activities, I will be communicating with all previous ATAC PIs to assist with the logistics of the study in order to get sites up and running. In the long-term I will also be involved in the data-management activities with use of the web-based electronic data capture system that has been developed to ensure that data being received is complete and of the highest quality. I am looking forward to working with all the clinicians that were involved in ATAC to successfully take LATTE forward.

Dr Norman Williams, CTG UCL

Having been closely involved in the ATAC Trial for eight years, it is a pleasure to see the next chapter unfold. I will be closely involved with the LATTE Executive Committee and LATTE Advisory Board, and will be the primary link with the international centres. With 381 sites around the world, it will be a challenge to maintain the high standard of data collection set by ATAC, but I'm confident this can be achieved with the excellent team at the CPTU.

Getting started

The South East Ethics Committee has recently given a favourable ethical opinion of the LATTE study and it has been confirmed that Site Specific Approval (SSA) is not required in order to participate. However, you will still need to seek R&D approval before commencing with the study.

We would like to register all sites by completion of a 'Start-Up Questionnaire'. This will allow us to collect up-to-date contact information for participating sites in order to begin communications for set-up of the study.

We have a stand and poster at the upcoming BASO meeting, to be held on 17-18th March in York where we hope to make contact with as many ATAC PIs as possible.

LATTE web-based electronic data capture (EDC) system

To manage patient data the LATTE Study is providing a secure web application. The web application will be accessible via the CPTUs Citrix™ Portal. The portal offers a high level of security with access to authorised users only and all data fully encrypted.

Using the web application offers several advantages over completion of paper forms :

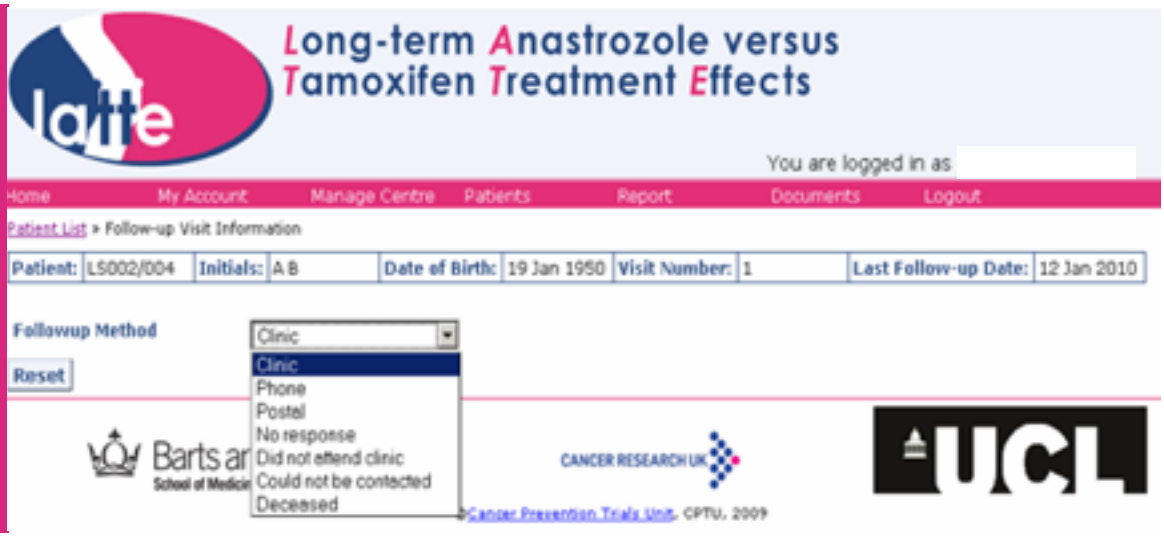
- View a customisable list of patients at your centre(s)
- Simple Wizard style forms to record follow-up visit information
- Generate summary reports for your centre(s)
- Access study documents
- Manage your contact information
- All data is fully backed up and a full audit trail is maintained.

CPTU Cancer Prevention Trials Unit uniting to prevent cancer

Barts and The London School of Medicine and Dentistry

UCL

LATTE website
A screenshot of the online system used to collect the data locally



When you have registered your participation for the LATTE Study, by completion of the Start-Up Questionnaire, you will have full on-line access to the library to access all relevant study documents as well as details of the patients at your site for on-line submission of the data.

The LATTE Operations Group (LOG) Contact Details

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Visit the LATTE website for all current news and information and for direct access to the CRFs for LATTE participants: www.cptu.org.uk/latte