

CTSU clinical trial follow-up service Privacy Notice

The CTSU clinical trial follow-up service

The CTSU clinical trial follow-up service has one aim, to support the conduct of individual participant data (IPD) meta-analyses of the comparative effects of different treatments for women with breast cancer. The CTSU clinical trial follow-up service receives follow-up data about participants in UK clinical trials and removes the identifying information about the participants before the data are processed for inclusion in the EBCTCG overview.

The Early Breast Cancer Trialists' Collaborative Group (EBCTCG)

The EBCTCG overview is a series of IPD meta-analyses. The project includes women diagnosed with operable breast cancer (or breast cancer which might become operable through the use of pre-surgical therapy) and enrolled on randomised trials comparing treatments for breast cancer, with recurrence or death as a principal outcome. Meta-analysis of results from randomised trials of the treatment of women with early breast cancer provides reliable and robust evidence to inform the thousands of decisions about the management of breast cancer that take place every day around the world.

The women who joined several important UK clinical trials included in the EBCTCG overview are no longer being actively followed up by the researchers who recruited them, or by their practitioners, for the outcomes measured for the original trials or those needed for the EBCTCG meta-analyses. Therefore, the only way that these participants' outcomes can be collected and added to the EBCTCG analyses is by linkage of their medical records via the NHS, by their information processing service, NHS Digital. If this is not done, the data on the women who agreed to join these trials will not be able to continue to contribute to the meta-analysis of long-term follow-up, and this opportunity to evaluate the long-term harms and benefits of treatment in a cost-effective way will be wasted.

The protocols of most of the randomised controlled trials included in the EBCTCG overview would require participants to give informed consent to long term follow-up of their treatment outcomes, including details of disease recurrence, adverse effects and death. However, in the earliest clinical trials for breast cancer treatment, explicit consent for long-term follow-up by data linkage was not sought at the time of randomisation. In circumstances such as this we can seek permission from the NHS Confidentiality Advisory Group to link, transfer, process and analyse the data without the knowledge or consent of the participants.

Linkage of your data by NHS Digital

Linkage of participants' data by NHS Digital via the CTSU clinical trial follow-up service is only for participants enrolled into ten UK clinical trials for breast cancer, enrolling 1948-1987, which are no longer being followed up by their relevant researchers or practitioners. Follow-up information from up to 1385 participants is still required to complete the data collection from these trials. Details of the trials can be found in the Appendix.

Long-term follow-up data from the clinical trials will be identified by NHS Digital using participant identity information provided by, or with the consent of the original trialists. The data will be

transferred to the CTSU Clinical Trial Follow-up Service where they are matched to the participants by name, date of birth, NHS number, address and details of the disease that have been collected previously and are now in the original study database. The new information will then be added to the EBCTCG analysis database. Personal data will be stored after the end of the study for less than three months. The study will end when all participants are confirmed to be deceased or permanently lost to follow-up.

Before analysing this complete dataset (including information already provided by trial participants with information from NHS Digital) personal identifiers will be removed. Importantly, whilst the information received is specific to each trial participant, no individual person will be identifiable in any publication arising from this work. Your personal data will not be shared with any 3rd parties and will not be used for any automated decision making or profiling. If you would like to have this data withdrawn, please contact the study team using the details given below.

The follow-up received from NHS digital consists of both Hospital Episode Statistics (HES) and Office of National Statistics (ONS) mortality data, and can include NHS identifiers, names, gender, date and place of birth, date and place of death, address, details of disease (such as cancer recurrence) and the date of inquest and causes of death.

Research Ethics Committee approval for the CTSU clinical trial follow-up service

This study has been reviewed and approved by the South Central - Oxford C Research Ethics Committee, reference number 19/SC/0590.

More information about the EBCTCG project can be found here:

<https://www.ctsuo.ox.ac.uk/research/ebctcg>

Research is a task that we perform in the public interest. The University of Oxford, as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible.

The legal basis for the processing and storage of personal data for the CTSU Clinical Trial Follow-up Service is that it is 'a task in the public interest' (article 6 (1) (e)) and, that sensitive personal data is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes (article 9 (2) (j), based on Article 89 (1)).

Under Section 251 of the NHS Act 2006, we have permission to conduct this study without consent.

We have special permission to conduct the CTSU clinical trial follow-up service without study-specific consent (i.e. link, transfer, process and analyse the data) from the Confidential Advisory Group. This permission is given under Section 251 of the National Health Service Act 2006 and its current regulations, the Health Service (Control of Patient Information Regulations 2002) (CAG reference number: 20/CAG/0143).

What to do next?

If you decide you do not want your data to be linked in this way you can withdraw from this follow-up, without affecting your current medical care, by contacting the study team, who would require your identifiers to then inform NHS Digital that you no longer wish to be part of the cohort. NHS Digital will then remove your identifiers from the study.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, [Where we have received special permission from the Confidential Advisory Group] however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data, specifically your right to lodge a complaint with a supervisory authority, is available at <https://compliance.web.ox.ac.uk/individual-rights> or by contacting our data protection officer at data.protection@admin.ox.ac.uk or the study team using the details below.

If you have further questions, please contact the study team at the following email address:-

Email: [bc.overview@ndph.ox.ac.uk]

Appendix: UK trials that were linked by CTSU-ctfs

- Ovarian Irradiation Trial, Part I: Entry JUN-1948 to DEC-1950; 189 participants; Principal Investigator Dr Paterson; Reported in: J Faculty Radio 10: 175-80 1959 (no further follow-up).
- Addenbrooke's Stage II: Entry OCT-1958 to MAY-1965 233 participants; Principal Investigator Dr John Haybittle ; Reported in: Lancet 2:1086-7 1971 (no further follow-up).
- Cardiff Trial: Entry SEP-1967 to JUN-1973; 200 participants; Principal Investigator Margaret Maureen Roberts; Reported in: Ann Surg Oncol 6(5):455-60 1999 (no further follow-up).
- Lister Trial: Entry SEP-1969 to SEP-1976; 534 participants; Principal Investigator L. Turner; Reported in: Ann R Coll Surg Engl 63(4)239-43 1981.
- Regional Breast Study 1 & 2: Entry MAR-1970 to OCT-1975; 1012 participants; Principal Investigator J. P. Lythgoe; 279 participants still being followed up in 1990 were linked in 2001; Reported in: Br J Surg 69(12) 693-6 1995.
- King's/Cambridge Radiotherapy (C.R.C. 1): Entry MAY-1970 to JUN-1975; 2800 participants; Principal Investigator M. Baum; a number of UK participants were linked in 1999; Reported in: World J Surg. 1994 Jan-Feb;18(1):117-22.
- Tamoxifen trial: Entry NOV-1976 to JUL-1982; 1005 participants; Principal Investigator Dr G. Ribeiro; Reported in: Br J Cancer 62(Suppl 12):16 1990.
- CMF/Tamoxifen Trial UK: Entry MAY-1978 to MAR-1984; 118 participants; Principal Investigator Dr L.F.N. Senanayake; Reported in: Lancet 2 (8412):1148-9 1984.

- C.R.C. Adjuvant Breast Trial (C.R.C. 2): Entry SEP-1980 to APR-1986; 2230 participants; Principal Investigator M. Baum; a number of UK participants were linked in 1999; Reported in: Br J Cancer 57(6):604-7 1988.
- Conservation Trial: Entry OCT-1982 to DEC-1987; 708 participants; Principal Investigator Dr G. Ribeiro; Reported in: Clin Oncol R Coll Radiol 5(5):278-83, 1993.