31 March 2018

Notice to patients who participated in JBCRG-04 (CREATE-X) study at participating hospitals

Voluntary organization JBCRG will use information from patients who participated in the above clinical study for the study which details are given below. We would appreciate your understanding and cooperation in this regard.

Study title	EBCTCG Meta-analysis
Principal study organization	EBCTCG (Early Breast Cancer Trialists' Collaborative Group) https://www.ctsu.ox.ac.uk/research/ebctcg
Study objectives	EBCTCG Meta-analysis is a large-scale integrated analysis of patients' background information and research data obtained through their participation in breast cancer clinical studies conducted worldwide. Its objectives are to investigate worldwide trends in breast cancer therapies, their efficacy and adverse effects, and examine breast cancer treatment modalities for the future.
Study subjects and types of information used	JBCRG received a request from EBCTCG to provide study data for patients who participated in JBCRG-04 (CREATE-X) "A phase III trial of adjuvant capecitabine monotherapy in breast cancer patients with pathologic residual tumors after neoadjuvant chemotherapy and resection of the primary tumor". The information to be provided is finalized data from the study that you participated, which include age, progression status and nature of cancer (e.g. tissue type, hormone receptor, HER2 expression) at the time of your participation, as well as method of administration, dosage, efficacy and adverse effects of the study drug during the study period. These will be anonymized data from which individuals cannot be identified. The data will be recorded on CDs or DVDs and sent to EBCTCG in Oxford, UK where it will be integrated with that from large numbers of patients who have participated in breast cancer clinical trials worldwide and analyzed.
Non-agreement to use of data in the analysis	In order to provide your data, you will not need to undergo any additional research and it will not cost anything. If you have any questions about the analysis, please ask them by the end of September 2019. Please also let us know by this date if you do not wish your data to be used and it will not be included in the analysis.
Contact in case of non-agreement to use of data	Because JBCRG only has anonymized data on patients, it may be difficult to respond if you contact us directly. Please be sure to ask any questions or notify us of non-agreement to the use of your data through your attending physician at the medical institution participating in JBCRG-04 (CREATE-X).

Ownership of intellectual property arising from the study and conflicts of interest	EBCTCG, the principal study organization, retains the rights to any new findings or intellectual property arising from the study. Similarly, all rights to intellectual property arising from JBCRG-04 (CREATE-X) are retained by JBCRG that conducted the study, and the study subjects have no ownership rights over intellectual property. Funding for the provision of data for the present study will come from the grant received by the voluntary organization JBCRG for JBCRG-04 (CREATE-X). The provider of the grant is Advanced Clinical Research Organization (ACRO). There are no conflicts of interest that may affect the study results and interpretation.
JBCRG-04 study organization	Voluntary Organization JBCRG Nihonbashi-koamicho 9-4, Chuo-ku, Tokyo 103-0016, Japan TEL: 81-3-6264-8873　FAX: 81-3-6264-8875
Medical institutions registering patients for JBCRG-04	Japan 62 sites, Korea 22 sites
Study investigators	JBCRG-04 (CREATE-X) Principal investigator Norikazu Masuda Dept of Surgery, Breast Oncology, NHO Osaka National Hospital 2-1-14 Hoenzaka, Chuo-ku, Osaka 540-0006, Japan TEL: 81-6-6942-1331 Representative of the study organization Chairman: Masakazu Toi Dept of Surgery (Breast Surgery), Graduate School of Medicine, Kyoto University, Kyoto, Japan 54 Shogoinkawaharacho, Sakyo-ku, Kyoto-shi, Kyoto 606-8507, Japan TEL: 81-75-751-3660
Remarks	