

To the patients and families who participated in the TERRA study

Taiho Pharmaceutical Co., Ltd. supports the "International Clinical Trial Data Integration Project - ARCAD Asia," conducted by the National Cancer Center and is providing the following information on patients who participated in the TERRA study to ARCAD Asia.

Although there is no personally identifiable information in the data to be provided, if you do not wish to have your information included, please contact us at the address below.

1. Eligibility

Patients who participated in the TERRA study between October 2013 and June 2016.

TERRA study: Randomized, Double-Blind, Phase III Study of TAS-102 Versus Placebo in Asian Patients with Metastatic Colorectal Cancer Refractory or Intolerable to Standard Chemotherapies.

2. Purpose and method of use of information

ARCAD Asia is collecting the data from clinical trials conducted mainly in Asia, by academic research groups and pharmaceutical companies at the "ARCAD Asia Data Center" (located in the National Cancer Center Hospital East). By integrating data from the clinical trials using a method called "data sharing", we will create a large database to accelerate drug and therapy development, and to contribute to future medical advances and society as a whole. Since the data were collected from clinical trials conducted in the past, no new information will be requested for this research.

Research period: Permission date to March 31, 2024

3. Type of information provided

The following data collected in the TERRA study:

Patient background (sex, age, race, previous treatment, among others), biomarker, blood test results, study treatment, outcome, and others

Specimen: None

The data provided by Taiho Pharmaceutical to ARCAD Asia do not include information that can identify patients. In addition, ARCAD Asia cannot identify patients by matching the data with other information. Furthermore, no individual will be identified in the reporting or publication of research results.

4. Scope of data users

The data described in Section 3 will be provided to ARCAD Asia for research.

Principal Investigator:

Atsushi Ohtsu, Director of National Cancer Center Hospital East

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ARCAD Asia Office:

Department of Data Science, National Cancer Center Hospital East

Address: 6-5-1 Kashiwanoha, Kashiwa-shi, Chiba 277-8577

E-mail: arcadasia_office●east.ncc.go.jp

(Please replace "●" with "@" when you send an email.)

5. Personnel and contact information

If you have any questions about our research, please contact us.

If you wish, you can request access to the research protocol and related materials, to the extent that it does not interfere with the protection of other participants' information and intellectual property.

If you or your representative do not consent to be used your information collected in the study in which you participated, please contact ARCAD Asia Office at the contact information address. However, please note that if the information has already been integrated to database of ARCAD Asia, we cannot delete your information even if you request us to do so.

Person responsible for information management:

Takahito Okubo, Head of Clinical Development/Medical Affairs Division

Taiho Pharmaceutical Co., Ltd.

Address: 1-27 Kandnishiki-cho, Chiyoda-ku, Tokyo 101-8444

Contact information:

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