For application for reexamination

Special Investigation for XALKORI CAPSULES

- Survey for *ALK* fusion gene-positive non-small cell lung cancer -

Implementation Guideline

Pfizer Japan Inc.

[redacted]

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Introduction

Xalkori Capsule (generic name: crizotinib) (hereinafter referred to as “this drug”) is an ATP-competitive kinase inhibitor that selectively inhibits a receptor tyrosine kinase (RTK) of the anaplastic lymphoma kinase (ALK) and its carcinogens (*ALK* fusion proteins and specific ALK mutants). The marketing authorization of this drug was obtained on March 30, 2012 for the treatment of *ALK* fusion gene-positive, unresectable advanced and recurrent non-small cell lung cancer.

A special investigation of Xalkori Capsule - Survey for *ALK* fusion gene-positive non-small cell lung cancer – (hereinafter referred to as “this survey”) will be conducted to detect or verify the occurrence of diseases, etc. caused by adverse drug reactions of this drug by type and information on quality, efficacy and safety under the actual use of the drug in daily medical care. The information obtained in this survey will be used to provide the proper use information and prepare the data for application for reexamination. For this reason, this survey must be conducted in compliance with the “Ministerial Ordinance Related to Standards for the Implementation of Post-Marketing Survey and Studies on Drugs” (Ministerial Ordinance No. 171 of the Ministry of Health, Labour and Welfare dated December 20, 2004). The patient data collected in this survey will be reported to the Ministry of Health, Labour and Welfare (MHLW) based on the Pharmaceutical Affairs Law. For the patients who developed adverse drug reactions, the information on drug names, adverse drug reactions, sex, age (generation), etc. may be published on the “Pharmaceuticals and Medical Devices Safety Information” and “Website of the Pharmaceutical and Medical Devices Information (http://www.info.pmda.go.jp)” as a list of patients. In addition, the collected patient data will be disclosed if there is a disclosure request to the MHLW based on the “Act on Access to Information Held by Administrative Organs” (Act No. 42 of May 14, 1999). In either case, however, since the information on names of physicians, sites, etc. is not subject to reporting, such information will not be posted or disclosed.

1 Objectives

This survey examines the safety and efficacy of this drug in daily medical care. It is also intended to understand the occurrence of unknown and known adverse drug reactions and under the actual use during the survey period and examine the necessity of conducting a new special investigation and/or post-marketing clinical study.

Based on the conditions of approval (because there is an extremely limited number of patients for domestic clinical studies, a use-result survey must be conducted for all patients until the data on a certain number of patients are collected to understand the background information on the patients using this drug and take necessary measures for proper use of this drug by collecting the data on the safety and efficacy of this drug early), this survey will be an all-patient registration survey until the data on a certain number of patients are collected after the marketing of this drug in order to verify the information on adverse drug reactions that may occur at an early stage after the use of this drug.

As the priority items to be surveyed, the occurrence of the following events will be studied.
(1) Interstitial lung disease
(2) QTc prolongation
(3) Bradycardia
(4) Hepatotoxicity
(5) Visual disturbance
(6) Neutropenia/leukopenia
(7) Neuropathy
(8) Complex renal cyst
(9) Photosensitivity

2 Patients to be surveyed

An all-patient registration survey will be conducted for all patients who will receive this drug (including the patients who have participated in the special medical care coverage) for a certain period of time. The indications and dosage and administration of this drug are as follows.

See the latest package insert when administering this drug.

Indications: *ALK* fusion gene-positive unresectable, advanced/recurrent non-small cell lung cancer

Dosage and administration: The usual adult dosage for oral use is 250 mg of crizotinib twice daily. The dosage may be decreased according to the patient condition.

3 Target sample size

The target sample size is 2000 patients with *ALK* fusion gene-positive non-small cell lung cancer treated with this drug (including the patients who have participated in the special medical care coverage).

〔Rationale for setting〕

The incidence of interstitial lung disease among the Japanese patients in the data of global clinical trials (Studies A8081001, A8081005, A8081007 and A8081014) was about 3.6% (4/111)*. Considering that the incidence of interstitial lung disease among the Japanese patients may be higher than that of the foreign patients, the target sample size was examined by assuming that the incidence of interstitial lung disease caused by this drug is about 4%.

By referring to the results of a prospective survey (special survey) of gefitinib, special investigation of erlotinib, etc., if the incidence of interstitial lung disease among the population with high risk for a certain factor (high-risk population) is more than twice the incidence of interstitial lung disease among the population with low risk for the same factor (low-risk population), we considered setting the sample size so as to detect this population with high probability and examined it based on the relations among the sample size, significance level and power necessary for a chi-square test.

When the significance level was 15%, a power curve nearly exhibited a plateau around 2000 patients. When the sample size was 2000, the power was 90% or higher even if the ratio of the sample size between the low-risk population and high-risk population was 1:2 or 2:1 and 86.3% even if the ratio of the sample size was 1:3. On the other hand, when the significance level was 5% with the sample size of 2000 patients, the power was 83.8%, 77.5% and 81.0% respectively when the ratio of the sample size was 1:1, 1:2 and 2:1. Furthermore, when the ratio was 1:3 and 3:1, the power was 68.4% and 75.8% respectively, demonstrating certain power.

Based on the above results, the target sample size of 2000 patients is also a sufficient size when examining risk factors that require attention by multivariate analyses such as a Cox proportional hazard model.

*Because Studies A8081007 and A8081014 are ongoing open-label randomized studies, half of the patients who were treated with the study drug as of December 6, 2011 were counted as the patients treated with crizotinib

4 Scheduled period of survey

The periods of implementation and registration will be set as follows:

Survey period : Date of release of this drug in 2012 - not to be set*

Registration period : Date of release of this drug in 2012 - not to be set*

*The survey and registration periods will continue until the final evaluation by the regulatory authority is obtained.

5 Survey methods

5.1 Survey method

The survey will be conducted in an all-patient registration survey method until the sample size after the marketing of this drug reaches 2000 patients (patients with *ALK* fusion gene-positive non-small cell lung cancer). In case of using this drug after December 4, 2014, only case registration will be continued. Based on the request of Pfizer Inc., in the case where it is necessary to collect additional information in cases with case registration using this drug after December 4, 2014, the investigative physician Describe the survey form.

5.2 Method of data collection

In this survey, the data are collected using the designated “survey form” provided by Pfizer Japan Inc. (hereinafter referred to as “sponsor”). The physician in charge of survey will promptly fill out the survey form after the end of the observation period for survey form parts, seal the survey form in an envelope and submit it to the sponsor. The specific procedures, methods of filling out, correcting and verifying the survey form shall be separately stipulated in the sample for entry, etc.

5.3 Patient registration

The physician in charge of survey will fill out a site name, medical department name, physician’s name, date of entry, contact information to verify the registration, patient identification number, patient’s initial (when necessary), date of birth (or age), (scheduled) start date of administration, use experience of Xalkori by this patient, contraindications, indications, careful administration and verification of other precautions in the “registration form” provided by the sponsor and register them prior to the start of administration.

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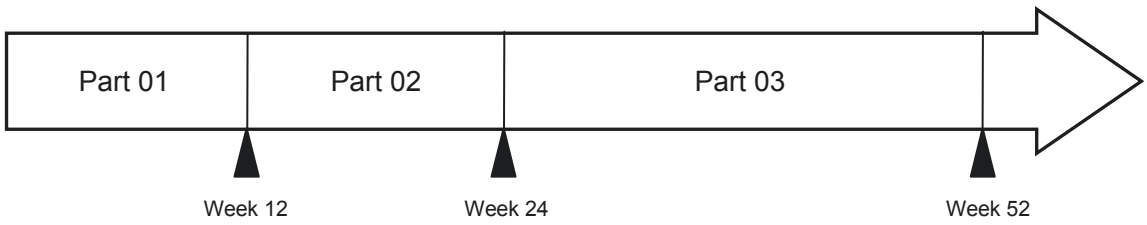
5.4 Observation period

The observation period is 52 weeks from the start date of administration of Xalkori. However, for the patients who completed or discontinued the administration of Xalkori, a period up to the date of completion or discontinuation will be the observation period.

In this survey, the following part-type survey forms for the observation period are used.

Part 01: From the start of administration until Week 12 (84 days)
Part 02: From Week 13 (85 days) until Week 24 (168 days)
Part 03: From Week 25 (169 days) until Week 52 (364 days)



5.5 Points to note when filling out, correcting and verifying the survey form

(1) Method of fill-out

The physician in charge of survey will verify the survey items and fill out the data with an immortal writing material such as a pen and ballpoint pen based on the medical records and results of various tests. For the test results, a copy of the record may be attached. However, masking, etc. should be used for personal information so that a patient’s personal information

cannot be identified but the patient's record such as a patient identification number can be determined.

(2) Method of correction

When correcting the content entered, the physician in charge of survey will draw a double line (=) so that the original content can be read and affix a correction seal. If there is an inquiry about the content from the sponsor, the physician in charge of survey will verify the aforementioned medical records again, correct the content in the survey form when necessary and submit it to the sponsor again. When correcting the content related to the evaluation of efficacy and safety, the reason(s) for correction and date of correction must be entered together in principle.

(3) Method of verification

After completing the entry and correction of all survey items, the physician in charge of survey will verify the entered survey form and re-survey form again and place his/her printed name and seal or sign them.

5.6 Entry of survey form and points to note in patients changing hospital

If this drug is continuously administered after the patient is transferred to another hospital, the following procedures shall be taken:

(1) Check "Change hospital/medical department" of discontinuation record in the survey form of the pretreatment site and enter the information of the transferred site.

(2) Verify the use experience of this drug in the patient record at the pretreatment site and enter the information of the pretreatment site.

(3) Verify the use experience of this drug in the survey form of the transferred site and enter the information of the pretreatment site.

(4) Enter the information after last visit at the pretreatment site in the survey form of the transferred site without omission.

(5) Handle the applicable patient as the same patient based on the information obtained with the registration form and survey form.

(6) The sponsor may make an inquiry about the information entered in the survey form when necessary.

6 Survey items and timing of survey

The physician in charge of survey will conduct this survey according to the following observation schedule. The physician in charge of survey will register the patients who meet the registration criteria after signing a contract of this survey, verify the data including the information on patient characteristics at the start of administration and fill out the survey form. The physician in charge of survey will verify the observation data after the end of the observation period for survey form parts during the observation period or at the time of discontinuation if the administration of this drug is discontinued prematurely, fill out the survey form, and submit it to the sponsor.

【Observation schedule】

Registration form	Survey form

Survey item \ Timing		At registration *1	Observation period			
			At start of administration (Part 01)	From start of administration until Week 12 (Part 01)	From Week 13 until Week 24 (Part 02)	From Week 25 until Week 52 (Part 03)
Patient information	ID number	●	○			
	Patient initial (when necessary)	●	○			
	Sex	●	○			
	Date of birth or age	●	○			
Patient characteristics	(Scheduled) start date of administration of Xalkori	●	○			
	Height/weight		●			
	Inpatient/outpatient		●			
	Target diseases, results of *ALK* test		●			
	Condition of tumor		●			
	General condition (ECOG PS)		●			
	Other patient characteristics (e.g. smoking history)		●			
	Implementation of imaging test of chest prior to the administration of Xalkori*2		●			
	Medical history		●			
	History of pretreatment (history of drug therapy, surgery, radiotherapy)		●			
Dosing record of Xalkori				●	●	●
Concomitant therapy (history of drug therapy, surgery, radiotherapy)				●	●	●
Laboratory test			●	●	●	●
Efficacy evaluation (objective tumor response)				●	●	●
Pregnancy				●	●	●
Discontinuation record				●	●	●
Verification of survival				●	●	●
Adverse events				●	●	●

●: Item for entry of data, ○: Item for reflection of data
*1 Items to be entered at the time of registering patients
*2 For laboratory findings, the findings prior to the start of administration shall be entered in the section of medical history. If any aggravation or new symptom is observed after the start of administration of this drug, they shall be entered in the adverse event sections.

6.1 Patient characteristics

Enter the following information at the start of administration of this drug in the survey form.
(1) Height, weight
(2) Division of inpatient/outpatient
(3) Target diseases
(4) Results of *ALK* test (*ALK* test method, date of test implemented, test results)
(5) Tumor condition (TNM classification of the target diseases, histopathological diagnosis)
(6) General condition (ECOG-PS)
(7) Other patient characteristics (smoking history, history of occupational and environmental exposure to asbestos, pneumoconiosis, administration of highly-concentrated oxygen for the

treatment of respiratory disease)
(8) Implementation of imaging test of chest prior to the start of administration of this drug
(9) Medical history (name of disease or syndrome, division of previous or ongoing disease)
(10) History of pretreatment for non-small cell lung cancer (history of drug therapy, surgery and radiotherapy)

Enter the following information from the start of administration of this drug until the observation period in the survey form.
Pregnancy and date of delivery/scheduled date of delivery [for women only]

Compare the occurrence of adverse drug reactions and serious adverse drug reactions in the patients with or without hepatic function disorder and renal impairment and examine the risk factors.

6.2 Dosing record of this drug

Regarding the use of this drug from the start of administration of this drug until the end of the observation period (or date of discontinuation), enter the following information. In this survey, the administration record of this drug is defined as the dosing record.
(1) One-time dosing amount
(2) Daily dosing frequency
(3) Dosing period
(4) Reason for change/washout

6.3 Concomitant drug therapy

Regarding the drugs other than this drug used from the start of administration of this drug until the end of the observation period (or date of discontinuation), enter the following information. If any adverse event is noted, enter the drugs administered from the start date until the onset of the adverse event and drugs administered for the treatment of the adverse event.
(1) Drug name
(2) Division of dosage form
(3) One-time dose, daily frequency of administration
(4) Administration period
(5) Procedures taken for the adverse event

6.4 Surgical history for non-small cell lung cancer

Regarding the history of surgery performed from prior to the administration of this drug until the end of the observation period (or date of discontinuation), enter the following information.
(1) Site (primary tumor, metastatic tumor)
(2) Date of implementation

6.5 History of radiotherapy for non-small cell lung cancer

Regarding the history of radiotherapy performed from prior to the administration of this drug until the end of the observation period (or date of discontinuation), enter the following information.
(1) Site
(2) Total dose
(3) Period of implementation

6.6 Laboratory test

Provide the test slips of the laboratory tests performed from prior to the administration of this drug until the end of the observation period (or date of discontinuation).

・Hematology test (red blood cell count, hemoglobin, white blood cell count, differential leukocyte count (neutrophils, eosinophils, basophils, monocytes, lymphocytes), platelet count)
・Biochemistry test (total bilirubin, AST (GOT), ALT (GPT), AL-P, BUN, serum creatinine)

6.7 Efficacy evaluation (objective tumor response)

Evaluate the efficacy of this drug using the items for response evaluation described in the "New Guidelines for Response Evaluation Criteria in Solid Tumors (RECIST) – Revised Version 1.1" for each survey form part and enter the results.

Determine the objective tumor response according to the Determination for Objective Tumor Response: RECIST Criteria. In the classification of tumor lesions at the start of administration of this drug, identify target lesions and non-target lesions, check the presence or absence of any new lesion in addition to the results of determination of the objective tumor response in each tumor lesion site during the observation period and determine the overall response.

(1) Presence or absence of target lesion at the start of administration of this drug (Yes, No)
(2) Evaluation after the start of administration of this drug
- Presence or absence of implementation
- Date of response evaluation
- Overall response (CR, PR, SD, PD, unevaluable)

6.8 Discontinuation record (reason for discontinuation)

Whether the treatment with this drug should be continued or not will be verified at the end of the observation period (or date of discontinuation). If the treatment with this drug cannot be continued, select and enter the applicable major reason for discontinuation from the following reasons. If the adverse event was selected, enter the data in the adverse event section.

(1) Insufficient clinical response
(2) Adverse event
(3) Patient death
(4) No return to hospital
(5) Change of hospital/medical department
(6) Other (in the case of "Other," enter the reason. Example: Patient's will, etc.)

Supplement: In the case of patient death, select "Patient death" in the verification of survival and enter the related information in the adverse event section. In the survey, a period from the start of administration of this drug until the date when the patient's death was confirmed regardless of the cause of death will be defined as a survival period.

6.9 Verification of survival

Verify the survival of patients at the end of the observation period (or date of discontinuation). If the death was confirmed, select the applicable major reason for death from the following reasons. If progression of non-small cell lung cancer or other was selected, enter the data in the adverse event section.

(1) Survival
(2) Death

[Cause of death]
- Progression of non-small cell lung cancer
- Other
- Unknown

6.10 Verification of adverse events corresponding to priority survey items

If no adverse event corresponds to priority survey items other than the adverse event(s) entered in the adverse event section, tick a check box.

6.11 Adverse events

Verify the occurrence of adverse events after the start date of administration of this drug until the end of the observation period (or date of discontinuation). If any adverse event was observed, the physician in charge of survey will take appropriate procedures, promptly inform the sponsor according to the “Report of Adverse Events” (Attachment 1) and, in principle, verify the outcome and progress of the adverse event until its symptom disappears. If “the patient or his partner became pregnant or if the physician in charge of survey learns the pregnancy during the administration of this drug regardless of the presence or absence of adverse events” and if the physician in charge of survey learns the additional information, the physician in charge of survey will contact the sponsor. See “Report of Adverse Events” (Attachment 1) for the details.

If the sponsor determines it necessary, the detailed survey will be performed separately.

(1) Occurrence of adverse event for the patients who developed intrauterine exposure, serious adverse drug reactions, adverse drug reactions not listed in the package inserts, etc.
(2) Adverse event name
(3) Onset date
(4) CTCAE v4.0 Grade (at worst)
(5) Procedures
(6) Seriousness
(7) Outcome of adverse event to date
(8) Causal association with this drug

If the adverse event is related to visual disturbance or laboratory test value, etc., enter the following information in addition to the above survey items.

<Visit to Department of Ophthalmology as a result of visual disturbance and change in CTCAE v4.0 Grade>
(1) Adverse event name of visual disturbance
(2) CTCAE v4.0 Grade at onset of adverse event
(3) CTCAE v4.0 Grade at worst of adverse event
(4) CTCAE v4.0 Grade at outcome of adverse event
(5) Visit to Department of Ophthalmology

<Test related to the adverse event>
(1) Test name
(2) Baseline at site
(3) Unit
(4) Date of measurement
(5) Result

Supplement: An adverse event is any untoward event (including clinically problematic abnormal fluctuations of laboratory test values) for patients that occurred after the administration of this drug regardless of the causal association with this drug. A serious adverse event is an event that (1) results in death, (2) is life-threatening, (3) requires inpatient hospitalization or prolongation of existing hospitalization, (4) results in persistent or significant disability/incapacity, (5) is a congenital anomaly/birth defect,, (6) is other medically important event, or (7) may lead to impairment or damage.

6.11.1 Detailed information of adverse events related to interstitial lung disease

If interstitial lung disease occurs, fill out the Appendix 2 (Interstitial Lung Disease) regardless of the causal association with this drug. The sponsor will ask to provide the results of chest CT and x-ray tests (image photos or data), while the physician in charge of survey will send the test results along with the survey form to the sponsor.

6.12 Priority survey items

The occurrence of the following priority survey items will be examined in this survey.

If the sponsor determines it necessary, the detailed survey will be performed for the patients who fall under the category of the priority survey items.

(1) Interstitial lung disease
(2) QTc prolongation
(3) Bradycardia
(4) Hepatotoxicity
(5) Visual disturbance
(6) Neutropenia/leukopenia
(7) Neuropathy
(8) Complex renal cyst
(9) Photosensitivity

(1) Interstitial lung disease

Collect the information on the occurrence (including seriousness), medical history (e.g. past history of interstitial lung disease, the disease condition), concomitant medications, procedures (including reaction to the procedures), progress after the procedures, duration from the start date of administration of this drug until the onset date, duration from the onset date until the date of recovery, and judging comments by the physician. Also, for the patients who developed interstitial lung disease, obtain the data of image findings of chest CT test, etc. related symptoms, treatment for interstitial lung disease and the effect and related tests including respiratory test. Verify the past history of interstitial lung disease or the disease condition, etc. at the time of registration of this drug and collect the information on the aforementioned occurrence, concomitant medications, etc. after the start of the administration. Based on the information collected from the registration and survey forms, evaluate the occurrence of interstitial lung disease caused by the administration of this drug. Furthermore, the patient characteristics will be tabulated, analyzed and evaluated by occurrence of interstitial lung disease.

(2) QTc prolongation

Collect the information on the occurrence, medical history, concomitant medications, procedures, progress after the procedures, duration from the start date of administration of this drug until the onset date, and judging comments by the physician. Also, obtain the data of ECG and electrolytes. Collect the information by verifying the past history of QTc prolongation at the time of registration of this drug and filling out the registration form. Based on the information collected from the registration and survey forms, evaluate the occurrence of QTc prolongation caused by the administration of this drug.

(3) Bradycardia

Collect the information on the occurrence, medical history, concomitant medications, procedures, progress after the procedures, duration from the start date of administration of this drug until the onset date, and judging comments by the physician. Also, obtain the data of heart rate and electrolytes. Based on the information collected from the survey form, evaluate the occurrence of bradycardia caused by the administration of this drug.

(4) Hepatotoxicity

Collect the information on the occurrence, medical history (e.g. past history of lung disease or the disease condition), presence or absence of aggravation of metastases to lung, concomitant medications, procedures, progress after the procedures, duration from the start date of administration of this drug until the onset date, biochemistry test (e.g. AST, ALT, total bilirubin), data of related tests (including hepatitis screening), and judging comments by the physician. Verify the presence or absence of hepatic function disorder at the time of registration of this drug and collect the information by filling the condition in the registration form. Based on the information collected from the registration and survey forms, evaluate the occurrence of hepatotoxicity caused by the administration of this drug. Furthermore, the patient characteristics will be tabulated, analyzed and evaluated by occurrence of hepatotoxicity.

(5) Visual disturbance

Collect the information on the occurrence, concomitant medications, procedures, progress after the procedures, duration from the start date of administration of this drug until the onset date, duration from the onset date until the date of recovery (duration of visual disturbance), changes in CTCAE v4.0 Grade, and judging comments by the physician. For the patients who visited a department of ophthalmology, obtain the date of visit, presence or absence of ophthalmologic examination, type and results of the ophthalmologic examination and the diagnosis by the ophthalmologist. Based on the information collected from the survey form, evaluate the occurrence of visual disturbance caused by the administration of this drug. Furthermore, the patient characteristics will be tabulated, analyzed and evaluated by occurrence of visual disturbance.

(6) Neutropenia/leukopenia

Collect the information on the occurrence, concomitant medications, procedures, progress after the procedures, duration from the start date of administration of this drug until the onset date, hematologgy test data (red blood cell count, hemoglobin, white blood cell count, differential leukocyte count, platelet count), and judging comments by the physician. At the time of registration of this drug, collect the baseline information of neutrophil count, platelet count and hemoglobin with the registration form. Based on the information collected from the registration and survey forms, evaluate the occurrence of neutropenia/leukopenia caused by the administration of this drug. Furthermore, the patient characteristics will be tabulated, analyzed and evaluated by occurrence of neutropenia/leukopenia.

(7) Neuropathy

Collect the information on the occurrence, concomitant medications, procedures, progress after the procedures, duration from the start date of administration of this drug until the onset date, and judging comments by the physician. Based on the information collected from the survey form, evaluate the occurrence of neuropathy caused by the administration of this drug. Furthermore, the patient characteristics will be tabulated, analyzed and evaluated by occurrence of neuropathy.

(8) Complex renal cyst

Collect the information on the occurrence, concomitant medications, procedures, progress after the procedures, duration from the start date of administration of this drug until the onset date, and judging comments by the physician. For the patients who developed complex renal cyst, obtain the data on related symptoms, urinalysis, abdominal CT test and renal biopsy. Based on the information collected from the survey form, evaluate the occurrence of complex renal cyst caused by the administration of this drug.

(9) Photosensitivity

Collect the information on the occurrence, concomitant medications, procedures, progress after the procedures, duration from the start date of administration of this drug until the onset date, and judging comments by the physician. Based on the information collected from the survey form, evaluate the occurrence of photosensitivity caused by the administration of this drug.

7 Analysis plan

7.1 Analysis set

Basically, the patients who were confirmed to have taken this drug at least once will be the subjects for safety analysis. Also, the patients who have at least one measurable lesion and received the efficacy evaluation will be the subjects for efficacy analysis according to the analysis plan which will be separately specified.

7.2 Analysis method

(1) Analysis for safety evaluation

Major analysis items will be the occurrence of adverse drug reactions and interstitial lung

disease. Also, the factors that affect the occurrence of adverse drug reactions and interstitial lung disease will be examined by tabulating the incidences of adverse drug reactions and interstitial lung disease by factor such as patient characteristics. For the priority survey items, the analysis method will be separately specified in the analysis plan according to the purpose of examination.

[redacted] CCI [redacted]

8 Publication of the results

Pfizer Japan, Inc. will fulfill its responsibility of publishing the survey results by posting the results of this survey on ClinicalStudyResults.org. Pfizer Japan, Inc. will publish either of the following survey results. When necessary, it will also publish the survey results at scientific meetings, in papers, etc. to provide the proper use information.

- Survey registered to www.clinicaltrials.gov (ClinicalTrials.gov) by Pfizer Japan, Inc., regardless of the reason for registration
- Survey that Pfizer Japan, Inc. determined to be scientifically and medically important results other than the above

The timing of publication will be determined depending on whether there is any country that obtained the marketing approval of a Pfizer product when the survey using this product was completed.

- In any country, Pfizer Japan, Inc will publish the results of the survey that includes the already approved Pfizer product within one year from the date when the data of the last subject last visit (LSLV) are locked.

Pfizer Japan, Inc. will post the following items on ClinicalStudyResults.org:

- Title of the implementation guideline for the post-marketing survey, etc., development phase, target disease
- Labeling of the approved product
- Summary of the survey results
- References of published papers
- Legal disclaimer

The publication of the survey results will be posted on ClinicalStudyResults.org (Pharmaceutical Research and Manufacturers of America (PhRMA) website synopsis (PWS)) according to the format specified in ICH E3.
If the publication of the survey results on ClinicalStudyResults.org may interfere with other planned posting of the survey results, instead of the summary of the survey results, a document that states that the publication of the results will be put on hold will be posted. The posting period will be two years from the publication of the survey results or the completion of the survey, whichever comes earlier.
Pfizer Japan, Inc. will quote only the published papers accessible from widely accepted and searchable databases of papers.

9 Contact information

Contact information for the survey contents:

Name	Pfizer Japan, Inc. Post-Marketing Survey Department
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10 Attachment

Attachment 1: Report of Adverse Events