DRUG USE INVESTIGATION FOR HIV INFECTION PATIENTS OF MARAVIROC

- HRD Joint Survey -

STATISTICAL ANALYSIS PLAN

CELSENTRI Tablets 150 mg Statistical Analysis Plan

Outsourced by	ViiV Healthcare K.K.
Product name	CELSENTRI Tablets 150 mg Drug Use Survey, Special Drug Use Survey for Pregnant Women
Prepared by	CMIC-PMS Co., Ltd. PPD

<General Definitions>

Re-examination period	
Number of report	Survey period
1st	2008/12/25 (H20) - 2009/2/5
2nd	2/6/2009 (H21) - 8/5/2009
3rd	8/6/2009 (H21) - 2/5/2010
4th	2/6/2010 (H22) - 8/5/2010
5th	8/6/2010 (H22) - 8/5/2011
6th	8/6/2011 (H23) - 8/5/2012
7th	8/6/2012 (H24) - 8/5/2013
8th	8/6/2013 (H25) - 8/5/2014
9th	8/6/2014 (H26) - 8/5/2015
10th	8/6/2015 (H27) - 8/5/2016
11th	8/6/2016 (H28) - 8/5/2017
12th	8/6/2017 (H29) - 8/5/2018
13th	8/6/2018 (H30) - 12/24/2018
Re-examination	12/25/2008 (H20) - 12/24/2018
Date conversion	When you calculate dates for aggregation, make the following replacement: Replace the date “AA=early in the month” with 05, “BB=middle of the month” with 15, “CC=late in the month” with 25, and “DD=around” with 01. Replace “20EEEEEE=continued” with “the outcome confirmation date of the patient”. If nothing is provided, enter “entry date”. The new survey does not have entries of 20EEEEEE, but enter 20EEEEEE for continued administration if “entry date” is found. When you need to replace any inappropriate date (such as Day 00), add the following process: When the date in “first administration date” is not appropriate as a date, choose the final date of the month. When the month and date in “first administration date” are not appropriate as a date, enter “1231”. When the date in “final administration date” is not appropriate as a date, enter “01”. When the date in “onset date of adverse event” is not appropriate, enter “01”. When the date in “laboratory test date” is “00” or “99”, enter “01”. Only a date after the approval date (=December 25, 2008) should be used for CELSENTRI Tablets (when the first administration date comes before the approval date, replace it with the approval date).
Date unit	A week has 7 days, a month has 30 days, and 1 year has 365 days.
Prior to administration	It should be within 30 days prior to the first administration of CELSENTRI Tablets and be the closest date to the first administration date (the administration date is also included).
Displayed digit	Decimal numbers should be rounded to the second decimal place.
Missing data	When aggregating “unknown” and “not provided”, count them collectively as “unknown/not provided”. Of note, separate “unknown” and “not provided” for “medical history” and “allergy history”.

MedDRA	Use MedDRA/J Version 21.0. Count PTs for aggregation and use primary for SOC.
Adverse events	Adverse events for which the "relationship" column with CELSENTRI Tablets is not checked or "no relationship" is checked among the events that occurred on or after the first administration date of the drug, plus, the adverse reactions that are defined below. But the decision is based on the ViiV Healthcare's company assessment. Of note, they also include the event for which you can't decide whether it occurred on the first administration date of CELSENTRI Tablets because of unknown date even after <General Definitions> "Date conversion" resulting from its inarticulate onset date. Overlapped events with the same PT in a patient should be counted as one event in accordance with <General Definitions> "Integration process".
Adverse reactions	The events for which the relationship with CELSENTRI Tablets cannot be ruled out. The decision is based on ViiV Healthcare K.K.'s company assessment.
Serious adverse events	"Serious" events in the seriousness criteria among the above "adverse events". The decision is based on ViiV Healthcare K.K.'s company assessment.
Co-administration	Co-administration refers to a drug concomitantly used for at least a day. Of note, if only one date is overlapped when two anti-HIV drugs are used on the same day (as the first administration for one and the final administration for the other), it should be regarded as "replacement" and not counted as a concomitant drug.
Integration process	Take the following integration process per PT.
	<When the events occurred on the same date>
[Seriousness]	Integrate into a more severe event.
[Relationship]	The same years: Integrate into the final year when the relationship was observed. Different years: Integrate into the final year.
[Outcome (outcome confirmation date)]	The same year: Death>Not recovered>Recovered with sequela>Unknown>Recovering>Recovered>Not provided Different years: Integrate into the final year.
	Of note, when the onset date is unknown or not provided, the event with the onset date should be selected.
	<When the events occurred on different dates>
[Onset date]	Select the initial onset date.
[Seriousness]	Integrate into a more severe event.
[Relationship]	Integrate into the date of the "related" event.
[Outcome (outcome confirmation date)]	The same year: Death>Not recovered>Recovered with sequela>Unknown>Recovering>Recovered>Not provided Different years: Integrate into the final year.
	Of note, when the onset date is unknown or not provided, the event with the onset date should be selected.
	<Processing order> Process [1]: Events which occurred in the same year and on the same date Process [2]: Events which occurred in different years but on the same date Process [3] Events which occurred in the same year but on different dates Process [4] Events which occurred in different years and on different dates.
Test	Exclude "unknown", "not provided" and "not assessable" from test. Do not conduct a test for the items with multiple answers. When $\chi 2$ test is conducted and the degree of freedom (DF) is 1, conduct Fisher's exact test as well for the item.

<Handling of items>

Number of sites for the survey	Department codes (per contract) are included in the DCF site code. Count the number of site as one.
Primary disease	Give priority to “1=HIV Infection” throughout a year. ”AIDS” should be regarded as “HIV Infection” in “2. Others”. Others should be “Others”. [Stratification] HIV Infection, Others
Sex	Use the value in the CRF at the first administration of CELSENTRI Tablets. [Stratification] Men, Women
Presence/absence of pregnancy	Patients who receive CELSENTRI Tablets for at least one day during pregnancy (if the date of last menstrual period (LMP) is unknown after LMP, see Week 0 of pregnancy or later; if both are unknown, see the pregnancy diagnosis date or later) among the patients in “Sex:3” (Pregnancy: present). Include the cases with “Women” in “Sex”. [Stratification] Absence, Presence, Unknown/not provided
Age	Calculate the Western-style age as of the initial administration date of CELSENTRI Tablets based on the date of birth. Of note, if the description only includes the year for date of birth in a site, describe it as “January 1”. If it only includes the year and the month, replace it with “the first date of the month”. If a “period of age” or “age” is provided in the “date of birth “column, select the “period of age” or “age” provided in the CRF when the patient was started on CELSENTRI Tablets only after confirmation that it is the data for the applicable year. [Stratification] [1] ≤14 years old, ≥15 and ≤64 years old, ≥65 years old, unknown/not provided [2] ≤9 years old, ≥10 and ≤19 years old, ≥20 and ≤29 years old, ≥30 and ≤39 years old, ≥40 and ≤49 years old, ≥50 and ≤59 years old, ≥60 and ≤69 years old, ≥70 years old, unknown/not provided
Inpatient/outpatient classification	Use the value in the CRF at the first administration of CELSENTRI Tablets. [Stratification] inpatient, outpatient, inpatient ⇔
Treatment history for HIV infection	Use the value in the CRF at the first administration of CELSENTRI Tablets. However, if an anti-HIV drug is administered prior to the initiation of CELSENTRI Tablets, select “2=present”. [Stratification] Absence, Presence, Unknown/not provided
Race	Use the value in the CRF at the first administration of CELSENTRI Tablets. [Stratification] Japanese, others, unknown/not provided
Route of infection	Use the value in the CRF at the first administration of CELSENTRI Tablets. <Multiple-answers are acceptable in this column> [Stratification] Blood product, Mother-to-child transmission, Medical accident, Sexual transmission, Others, Unknown/not provided
Duration of disease	Calculate the years from infection to the first administration date. Display the minimum and the maximum as well. [Stratification] ≤1 year, >1 year and ≤2 years, >2 years and ≤3 years, >3 years and ≤4 years, ≥5 years, unknown/not provided
Medical history	Use the value in the CRF at the first administration of CELSENTRI Tablets. If there is an event that both occurred and recovered before the first administration of CELSENTRI Tablets in the ‘adverse event’ column, regard it as “present”. [Stratification] Absence, Presence, Unknown/not provided
Presence/absence of allergy	Use the presence/absence of allergy provided in the CRF at the first administration of CELSENTRI Tablets. [Stratification] Absence, Presence, Unknown/not provided
Complications	Use the complications provided in the CRF at the first administration of CELSENTRI Tablets. The events that occurred and did not recover before the first administration of CELSENTRI Tablets in the ‘adverse event’ column. [Stratification] Absence, Presence, Unknown/not provided
Type of complications	Complications provided in the CRF at the first administration of CELSENTRI Tablets <Multiple-answers are acceptable in this column> In addition, reflect the ViiV Healthcare K.K.’s instruction for data amendment. [Stratification] • ”Haemophilia”: complications are present “1. Haemophilia”

	•”Liver disorder”: the disease selected as liver disorder in ‘complication is present’: 3. Hepatitis A”, “4. Hepatitis B”, “5. Hepatitis C”, “6. Other liver disorders”, or “8. Others”
The mean daily dose	The mean dose for “administration period” Even if “administration period” is unknown, the provided value should be regarded as the mean when there is no change in “the dose”. [Stratification] >minimum and < 2 tablets, 2 tablets, >2 tablets and <maximum, unknown/not provided
Dosing frequency	Calculate the number of dosing in a day. [Stratification] 1, 2, ≥3 and ≤maximum, unknown/not provided
Administration period	∑ (final administration date - first administration date+1). Exclude the washout period. [Stratification] ≤180 days, >180 and ≤365 日、>365 and ≤730 日、>730, unknown/not provided
Administration period <cumulative>	Count “the number of patients” by accumulating “administration period”, count “the number of patients with adverse reactions” based on the “administration period” until the first adverse reaction occurred, and count “the number of adverse reactions” based on the “administration period” until the applicable adverse reaction occurred. Exclude the washout period. [Stratification] ≤180 days, >180 and ≤365 日、>365 and ≤730 日、>730, unknown/not provided
Total dose	∑ {(Final administration date - First administration date+1) ×a daily dose}. Exclude the washout period.[Stratification]≤360 tablets, >360 tablets and ≤730 tablets, >730 tablets and ≤1460 tablets, >1460 tablets, unknown/not provided
Total dose <cumulative>	Count “the number of patients” by accumulating “total dose”, count “the number of patients with adverse reactions” based on the “total dose” until the first adverse reaction occurred, and count “the number of adverse reactions” based on the “total dose” until the applicable adverse reaction occurred. Exclude the washout period. [Stratification] ≤360 tablets, >360 tablets and ≤730 tablets, >730 tablets and ≤1460 tablets, >1460 tablets, unknown/not provided
Continued/discontinued	Display ‘continued/suspended’ of the final administration period throughout a year. [Stratification] Continued, Suspended, Unknown/not provided
Presence/absence of concomitant drugs	If there is a drug concomitantly used in the “administration period” of CELSENTRI Tablets, select “2=present”. If there is a drug concomitantly used at least for a day, select “2=present”. Of note, if only one date is overlapped when two anti-HIV drugs are used on the same day (as the first administration for one and the final administration for the other), it should be regarded as “replacement” and not handled as a concomitant drug. [Stratification] Absence, Presence, Unknown/not provided
Number of concomitant drugs	Number of types of concomitant drugs used in the “administration period” of CELSENTRI Tablets Drugs concomitantly used at least for a day. Of note, if only one date is overlapped when two anti-HIV drugs are used on the same day (as the first administration for one and the final administration for the other), it should be regarded as “replacement” and not counted as a concomitant drug. [Stratification] ≤2 drugs, ≥3 and ≤5 drugs, ≥6 drugs
Type of concomitant drugs	Count the breakdowns of designated concomitant drugs. Of note, when a patient used multiple drugs in the same classification, count the drugs as one. <Multiple-answers are acceptable in this column> [Stratification] Anti-HIV drug, Other anti-virus drugs, Others

Number of concomitantly-used anti-HIV drugs	Number of types of anti-HIV drugs used in the "administration period" of CELSENTRI Tablets Drugs concomitantly used at least for a day. Of note, if only one date is overlapped when two anti-HIV drugs are used on the same day (as the first administration for one and the final administration for the other), it should be regarded as "replacement" and not counted as a concomitant drug. [Stratification] a single-use drug, 1 drug, 2 drugs, 3 drugs, ≥4 drugs
Type of concomitantly-used anti-HIV drugs	Count the breakdowns of designated concomitantly-used anti-HIV drugs. Of note, when a patient used multiple drugs in the same classification, count the drugs as one. <Multiple-answers are acceptable in this column> [Stratification] Nucleoside reverse transcriptase inhibitor, non-nucleoside reverse transcriptase inhibitor, protease inhibitor and integrase inhibitor
Presence/absence of a concomitant CYP3A inducer	Presence/absence of designated CYP3A inducers that are concomitantly used (See the sheet "A list of CYP3A inducers"). [Stratification] Concomitant CYP3A inducer "present", Concomitant CYP3A inducer "absent"
Haemophilia	"Present" should be selected when the codes applicable to haemophilia are included in the complication classification "1. haemophilia" or "8. Others" provided in the CRF at the first administration of CELSENTRI Tablets. [Stratification] Absence, Presence, Unknown/not provided
Classification of haemophilia	Classify it into "present" for the presence/absence of haemophilia. Classify non-A or non-B as "others". For the classification, give priority to the value provided in the CRF at the first administration of CELSENTRI Tablets. [Stratification] A, B, Others
CDC classification of seriousness prior to administration	It should be within 30 days prior to the first administration of CELSENTRI Tablets and the closest date to the first administration date should be displayed (the administration date is also included). Of note, if you cannot enter the value because no such value is available within 30 days before the first administration of CELSENTRI Tablets, the applicable value should be entered only when the value obtained prior to the first administration is the same as the one after the administration was started (The number of days does not matter. Note that the value should be provided in the survey form of the contract year). [Stratification] A, B, C, Unknown/not provided, P-0, P-1, P-2, Unknown/not provided
Tropism classification at the first administration of CELSENTRI Tablets.	Display the value obtained on the closest date to the first administration date of CELSENTRI Tablets within 30 days before/after the first administration. Display the earlier value obtained for this if the same values are found on the same dates both before and after the first administration. [Stratification] R5, X4, DM, NR, Not implemented* *If it was not conducted, separately record the reason for this (Prepare a list of the reasons why the tropism assay was not conducted).
Presence/absence of concomitant treatment	If any concomitant treatment was given in the "administration period" of CELSENTRI Tablets (for ≥1 day), select "present". [Stratification] Absence, Presence, Unknown/not provided
Presence/absence of blood coagulation factor	Count the presence/absence of drugs administered while the patient was on CELSENTRI Tablets 150 mg (the drugs with the concomitant drug codes {6343406, 6343409, 6343429, 6343430, 6343414, 6343431, 6343432, 6343434} on the top). In addition, display the presence/absence when "present" was selected for the presence/absence of haemophilia. [Stratification] Absence, Presence, Unknown/not provided

*When the minimum/maximum are specified in the stratification of the mock-up, display the minimum/maximum of each item.

<<Handling of cases>>

Patients whose survey form was collected	On March 26, 2018, the data on all the patients registered during this survey period were locked. Therefore, they are the patients whose survey form was collected as of March 26, 2018.
Patients in the safety analysis group	Patients excluded from the patients applicable to the following [Exclusion criteria from the safety analysis group] (Note that the patients with adverse reactions are not excluded). [Exclusion criteria from the safety analysis group] [1] Not visited after the first visit ⇒Patients whose survey form is composed of 1 volume alone, with "Outcome of patient" of "1. Not visited" or "2. Transferred", and also with their first administration of CELSENTRI Tablets = the outcome confirmation date in "Outcome of patient". [2] Not administered ⇒Patients whose administration of CELSENTRI Tablets cannot be traced since the approval date (=December 25, 2008). [3] Unable to re-survey adverse events ⇒ "8 Unknown" and "0. Not provided" for the presence/absence of adverse events"
Patients in the efficacy analysis group	The remaining patients after those applicable to the following [Exclusion criteria from the efficacy analysis group] are excluded from the safety analysis group. [Exclusion criteria from the efficacy analysis group] [1] Patients who used CELSENTRI for a purpose other than "Indication". Patients whose "Primary disease" is not "1. HIV infection" or "AIDS" in "2. Others". [2] Patients with no descriptions on either the number of CD4 or RNA copy around the administration.

<<Preliminary process>>

[1] AE matching
Conduct AE matching in accordance with "HRD Collaborative Survey/CELSENTRI Tablets 150 mg Drug Use Survey, Special Drug Use Survey for Pregnant Women Matching Specifications Ver.1.0", and assess the adverse events specified by ViiV Healthcare K.K. as <general definition> adverse events.

[2] A list of unknown administration period of other drugs
Prepare a list regarding other drugs with the first or final administration date unknown (after date conversion of <General Definitions>) and follow the instructions of ViiV Healthcare K.K. for the drugs to be handled as a concomitant drug.
* See the sheet "A list of other drugs with administration period unknown" for the mock-up.

[3] A list of replacement candidates of complications/medical history
Present a list that shows the events applicable to the following <criteria> as a replacement candidate for complications/medical history among all adverse events provided in the survey form, and follow the instructions of ViiV Healthcare K.K. for the events to be replaced as a complication or medical history.
<Conditions>
- Medical history: Adverse events (irrespective of the relationship) that occurred before the first administration date of CELSENTRI Tablets (not inclusive of the first date) and recovered or are recovering as of the first administration date (the outcome confirmation date comes before the first administration date).
- Complications: Adverse events that occurred before the first administration date of CELSENTRI Tablets (not inclusive of the first date) and are not applicable to the above criteria for medical history (irrespective of the relationship).

*See the sheets "A list of adverse events (complications/medical history of replacement candidates)" and "A list of adverse events (complications/medical history of replacement candidates/the onset date unknown)" for the mock-up.

<<Type of Tables>>

*Prepare all the following tables for the drug use result survey, and a list of patient summary for the survey and Attachment Form 10 (the aggregation combined with the drug use result survey) only for the special drug use result survey.

Reason for unconcluded contract by site	Prepare the reason per site for unconcluded contract.

1) Table for "All registered patients"

Patient composition chart	Display the number of site that concluded the contract per year, the number of patients with the registration form, the number of registered volumes per year, the number of patients whose survey form was collected, and the number of survey-form volumes. Also display the number of patients whose survey form was not collected, the number of patients excluded from the safety analysis (the number of patients per reason for exclusion), the number of patients in the safety analysis group, the number of patients excluded from the efficacy analysis (the number of patients per reason for exclusion), the number of patients in the efficacy analysis group.
Pick up the same case numbers	Pick up the case numbers by setting a flag per patient for the patients excluded from registration, the patients excluded from the safety analysis, the patients excluded from the efficacy analysis, the patients whose survey form was not collected, and the patients whose data was not locked. Then, display the patient registration numbers per year.

2) Table for "Patients whose survey form was collected"

A list of excluded patients	Display the designated items in the mock-up and patient registration numbers per reason for exclusion of patients excluded from the safety analysis or from the efficacy analysis.
Patient composition ratio	Display the number of patients and the patient composition ratio for the following patient background items. Follow the above <<Handling of Items>> for the definitions of each item per background. ◎ Displayed items: primary disease, sex, presence/absence of pregnancy, age, inpatient/outpatient classification, treatment history of HIV infection, race, route of transmission, duration of disease, medical history, allergy, complication, type of complication, renal disorder, liver disorder, the mean daily dose, administration period, administration period [cumulative], total dose, total dose [cumulative], continued/discontinued, concomitant drug, number of concomitant drugs, type of concomitant drugs, number of concomitant anti-HIV drugs, type of concomitant anti-HIV drugs, presence/absence of CYP3A inducer, presence/absence of haemophilia, haemophilia AB, CDC classification of severity prior to administration, tropism classification at the first administration, concomitant treatment, blood coagulation factor (all cases and the cases with haemophilia) Calculate the minimum and the maximum for age, duration of disease, the mean daily dose, administration period, total dose while calculate the mean and the standard deviation for age as well (Of note, as to the description age for example, calculate the age of a patient in his 30s will be calculated as 30 years old).
Line list (Basic patient-background data)	Retrieve the items provided in the mock-up from CELSENTRI-Tablets data base. Of note, display the calculated or edited values for the items with (calculate result) provided under the item name in the mock-up.
A list of the reasons why the tropism assay was not conducted	Pick up the patients who did not undergo the tropism assay and retrieve the reasons why the test was not conducted.
A list of the patient summary for the survey	Prepare the list based on the sheet "A list of the patient summary for the survey". See "166272A1" and "166272B1" in the mock-up.

3) Table for “Patients in the safety analysis group”.

Attachment Form 2	Display the aggregation results of adverse reactions in <General Definitions> in accordance with the Safety Periodical Report Green Book. Overlapped adverse reactions with the same adverse reaction name (PT) in a patient should be counted as one event in accordance with <General Definitions> “Integration process”. Display the columns of “Cumulative results in Drug Use Result Survey” and “Total” only per “Survey period” provided in <General Definitions>. Leave the ‘status until approval’ column blank. Display System Organ Class (SOC) in the order of the international agreement and Preferred Terms in the order of encoded PTs.
Attachment Form 2-2 (Attachment Form 10 as the re-examination application document)	Display the aggregation results of serious adverse events in <General Definitions> in accordance with the Safety Periodical Report Green Book. Overlapped adverse events with the same adverse event name (PT) in a patient should be counted as one event in accordance with <General Definitions> “Integration process”. Display the columns of “Cumulative results” and “Total” only per “Survey period” provided in <General Definitions>. Leave the ‘status until approval’ column blank. Display System Organ Class (SOC) in the order of the international agreement and Preferred Terms in the order of encoded PTs. *Aggregate it with the number of patients in the special drug use survey for pregnant women.
*A list of adverse events	Prepare a list for adverse events in <General Definitions>.◎ Displayed items: [1] patient number, [2]repeat, [3] adverse event name (the reported name, and each code and the name of SOC, PT and LLT), [4] seriousness (company assessment, physician’s assessment), [5] expected/unexpected, [6] the first administration date of CELSENTRI Tablets, [7] the onset date, [8] days to the onset, [9] outcome, [10] relationship with CELSENTRI, [11] pediatrics (calculated), the elderly (calculated), renal disorder (calculated), liver disorder (calculated), pregnant women (calculated), each flag of haemophilia (calculated), male/female patient, patient’s age
*A list of adverse reactions per patient background, etc.	Prepare a list for adverse reactions in <General Definitions>. ◎ Displayed items: No., patient registration number, age, pediatrics, the elderly, race, presence/absence of pregnancy, presence/absence of complications, haemophilia, renal disorder, hepatitis A, hepatitis B, hepatitis C, others, liver disorder, syphilis, others, presence/absence of haemophilia, presence/absence of liver disorder, presence/absence of renal disorder, name of complication, presence/absence of allergy, presence/absence of concomitant treatment, name of concomitant treatment, presence/absence of concomitant drugs, number of concomitant drugs, presence/absence of concomitant anti-HIV drugs, number of concomitant anti-HIV drugs, administration period, long-term administration, presence/absence of adverse events, presence/absence of adverse reactions, name of adverse reactions (PT), seriousness, outcome, days to the onset, relationship with CELSENTRI
Incidence of adverse reactions per patient background	Prepare a table of incidence of adverse reactions on the following patient-background items: Follow the above <<Handling of Items>> for the definitions of each item per background. ◎ Displayeditems: primary disease, sex, presence/absence of pregnancy, age, inpatient/outpatient classification, treatment history of HIV infection, race, route of transmission, duration of disease, medical history, allergy, complication, type of complication, renal disorder, liver disorder, the mean daily dose, administration period, administration period [cumulative], total dose, total dose [cumulative], continued/discontinued, concomitant drug, number of concomitant drugs, type of concomitant drugs, number of concomitant anti-HIV drugs, type of concomitant anti-HIV drugs, presence/absence of CYP3A inducer, presence/absence of haemophilia, haemophilia AB, CDC classification of severity prior to administration, tropism classification at the first administration, concomitant treatment, blood coagulation factor (all cases and the cases with haemophilia) Calculate the minimum and the maximum for age, duration of disease, the mean daily dose, administration period, total dose while calculate the

	mean and the standard deviation for age as well (Of note, as to the description age for example, calculate the age of a patient in his 30s will be calculated as 30 years old).
Data on the incidence of adverse reactions per patient background	Display the incidence of adverse reactions per patient background for each patient.
A list of the onset status of adverse reactions/infections per patient background	Prepare a list of the onset status of adverse reactions/infections for each patient background item below. Follow 'adverse reactions' of <General Definitions> for the onset status of adverse reactions while follow the above <Handling of Items> for the definition of each patient-background item. ◎ Displayed items: primary disease, sex, presence/absence of pregnancy, age, inpatient/outpatient classification, treatment history of HIV infection, race, route of transmission, duration of disease, medical history, allergy, complication, type of complication, renal disorder, liver disorder, the mean daily dose, administration period, administration period [cumulative], total dose, total dose [cumulative], continued/discontinued, concomitant drug, number of concomitant drugs, type of concomitant drugs, number of concomitant anti-HIV drugs, type of concomitant anti-HIV drugs, presence/absence of haemophilia, haemophilia AB, CDC classification of severity prior to administration, concomitant treatment, blood coagulation factor (all cases and the cases with haemophilia)
Number of days to administer until the day on which adverse reactions first occurred	Prepare a table by number of days ≦180 days, 180 days< ≦365 days, 365 days< ≦730 days, 730 days<
The incidence of adverse reactions per concomitant drug	Prepare a table of incidence of adverse reactions regarding concomitant drugs per drug code (the first 7 digits). Follow "Co-administration" of <General Definitions> for the definition of co-administration.
A table of patient numbers per concomitant drug	Prepare the patient registration numbers for each drug code (the first 7 digits) regarding concomitant drugs with and without patients with adverse reactions. Follow "Co-administration" of <General Definitions> for the definition of co-administration.
The incidence of adverse reactions per complication	Prepare a table of incidence of adverse reactions per PT regarding complications and other contents. The definition of complications is applied to the patients with "complications" of <Definitions of Items>.

In the list of *, use a row for an adverse reaction; enter multiple adverse reactions in the equivalent number of rows for a patient. Entry of a patient number, etc. should be repeated.

4) Table for "Patients in the efficacy analysis group"

A table and a chart of changes in HIV-RNA load/CD4	Prepare a chart and table on the changes in HIV-RNA load/CD4 in patients with and without treatment history, with and without concomitant CYP3A inhibitors, sex, with and without complications、with and without concomitant drugs, CDC classification and for all patients in the efficacy analysis group. Pre-administration (Month 0) should be the most recent date within 30 days before administration including the first administration date. For post-administration (Month 3, 6, 9, etc.), choose the value obtained on the most recent date within ±45 days from each point of Month 3, 6, 9, etc. If a "test value" is missing either before or after administrations, it should not be included in the chart. Use a line chart with test values on the y-axis and months after administration (for every 3 months) on the x-axis. For each point, extend the whisker in a single direction to show the SD value. When you have n=1 for each point, display it with a dot without connecting it with a line. Of note, for the maximum number of HIV-RNA copies detected, replace it with 399 from the initiation of survey to March, 2008, with 39 from April, 2008 to 2010 and with 19 in and after 2011 (depends on the site). Handle the encoded values, etc. as follows: Replace the values with inequality sign with the following [1] to [3] in calculation:

	[1] <400: The value that you subtract 1 from the figure without inequality sign. Note that the inequality sign must be removed from the figures with inequality sign. For example: change “<20” to “19”, “<40” to “39”, “≤20” to “20”, “≤40” to “40” [2] ≥400 and <100000: Missing [3] ≥100000: the value without inequality sign. For integer values less than 400 with no inequality sign, use them as they are without replacement.
Patients included in the chart [data in each plot]	Display the patient registration numbers and test results for each point of Month 0, 3, 6, 9, etc. to the number of HIV-RNA copies and CD4, the output data in the above graph.

5) Changes in tropism

For the patients who underwent a tropism assay (the patients whose tropism had been classified when the administration was started), prepare a list of their tropism assay results obtained within ±45 days of each point at Month 3, 6, 9, etc. of administration.

NOTE: These table forms may be subject to change due to the aggregated results or the relevant system.