Title: NINLARO Capsules Drug Use-Results Survey (All-Case Surveillance)
"Relapsed/Refractory Multiple Myeloma"

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Certain information within this statistical analysis plan has been redacted (ie, specific content is masked irreversibly from view with a black bar) to protect either personally identifiable information or company confidential information.

Note; This document was translated into English as the language on original version was Japanese.

Statistical Analysis Plan

Drug Use-Results Survey of Ninlaro Capsules (All-case Surveillance)
Relapsed or refractory multiple myeloma
(Final analysis)

Takeda Pharmaceutical Company Limited. Japan Development Center
Head of Biostatistics Office

Seal

Years Month Day

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LIST OF TERMS AND ABBREVIATIONS

- NINLARO capsules: Ninlaro capsules are abbreviated as NINLARO capsules.
- Adverse events: adverse events that occurred after administration of NINLARO capsules.
- Adverse drug reactions, etc.: Abbreviation for the term "adverse drug reactions/infections." Adverse events of which causal relationship to NINLARO capsules is not considered "not related." In this statistical analysis plan, the term "adverse drug reactions/infections" will be used in the title, and "adverse drug reactions, etc." will be used in the text and tables.
- Serious Adverse Events:
  - Investigation: An adverse event judged as "serious" by the investigator. Events listed in the Takeda Medically Significant AE List in Appendix 2 of the protocol for Post Marketing Surveillance will be handled as "serious" even if the assessment by the investigator is "nonserious."
- Patients whose survey form was not collected: Patients whose survey form was not collected among registered patients
- Patients whose CRFs were collected: Patients whose CRFs were collected among registered patients
- End Status:
  - Completed: Continue treatment after Cycle 7 selected for "Continue/discontinue treatment with NINLARO capsules."
  - Discontinuation: Discontinuation of administration before Cycle 6 was selected for "Continuation/discontinuation of administration of NINLARO capsules."
- Percentage (%)
  - Incidence of adverse events or adverse drug reactions, etc., or incidence of them:
    Round the second decimal place and display to the second decimal place.
  - Other than the above:
    Round the second decimal place and display to the first decimal place.
- Summary statistics
  - Mean, median, quantiles 14 and 34:
    The source data will be rounded to the first decimal place and displayed.
  - Standard deviation:
    The data will be rounded to the second decimal place of the source data.
  - Min and Max:
    The same number of digits as that of the target data will be displayed.
- Overall: All patients in the relevant analysis sets.
- Completed subjects: Subjects who completed this study.
- Discontinued patients: Patients who discontinued this study.
- BSA: Calculate using the following formula:.
  BSA=$\sqrt{(\text{height(cm)} \times weight(\text{kg}))/3600}$

- Initial dose of NINLARO capsules: The dose at the time NINLARO capsules is administered for the first time in a cycle.
- Lenalidomide Initial Dose: The dose of lenalidomide that was administered for the first time in the cycle when NINLARO capsules was administered. However, if all doses of lenalidomide within the same cycle are missing, the dose will be set to 0 mg.
- Dexamethasone Initial Dose: The dose of dexamethasone that was first administered in the cycle when NINLARO capsules was first administered. However, if all doses of dexamethasone within the same cycle are missing, 0 mg will be used.
- NINLARO capsules mean dose per dosing: Calculate using the following formula.

  Average dose of NINLARO capsules = Total dose of NINLARO capsules/(number of cycles × 3)
- NINLARO capsules RDI (Relative Dose Intensity): Calculate using the following formula.

  NINLARO capsules RDI (%) = (Total Dose of NINLARO capsules (mg)/Total duration of treatment (weeks)) /

  ((Number of cycles implemented × 4 mg × 3 times)/(Number of actual cycles × 4 weeks)) × 100

  The total of duration of treatment shall be as follows.

  (Day 1 of the -1 last cycle + Day 28)/7
- Lenalidomide Average dose per administration: Calculate using the following formula:.

  Average dose of lenalidomide = total dose of lenalidomide/(number of cycles × 21)
- Lenalidomide RDI (Relative Dose Intensity): Calculate using the following formula:.

  Lenalidomide RDI (%) = (Total Lenalidomide Dose (mg)/Total duration of treatment (weeks)/(Number of cycles × 25 mg × 21 cycles)/(Number of actual cycles × 4 weeks) × 100 The total of duration of treatment shall be as follows.

  (Day 1 of the -1 last cycle + Day 28)/7
- Mean dexamethasone dose per administration: Calculate using the following formula:.

  Average dose of dexamethasone = total dose of dexamethasone/(number of cycles × 4)
- Grade of liver dysfunction:
  - Normal: total bilirubin ≤ normal [1.2 (mg/dL)]
  - Mild: Total bilirubin > ULN to ≤ 1.5 × ULN
  - Moderate: total bilirubin > 1.5 × ULN to ≤ 3 × ULN
  - Severe: total bilirubin > 3 × ULN
- Grade of renal impairment:

  If Ccr is not missing, set as follows.
  - Normal: Ccr ≥ 90 mL/min
  - Mild: Ccr ≥ 60 and < 90 mL/min
  - Moderate: Ccr ≥ 30 and < 60 mL/min
  - Severe: Ccr ≥ 15 and < 30 mL/min
  - End-stage renal failure: Ccr < 15 mL/min

  If Ccr is missing, set as follows:.
  - Normal: eGFR ≥ 90 mL/min/1.73 m^2
  - Mild: eGFR ≥ 60 mL/min/1.73 m^2 and < 90 mL/min/1.73 m^2
  - Moderate: eGFR ≥ 30 mL/min/1.73 m^2 and < 60 mL/min/1.73 m^2

- Severe: eGFR ≥ 15 mL/min/1.73 m ^{2} and < 30 mL/min/1.73 m ^{2}
- End-stage renal failure: eGFR of 15 mL/min/1.73 m < ^{2}

- Medications used of preventive drugs for infection and recurrent herpes zoster:

  Medications used of preventive drugs for infection and recurrent herpes zoster that correspond to the following

  - Famciclovir: Last 7 digits of drug code is 6250031
  - Valaciclovir: the first 7 digits of the drug code are 6250019
  - Aciclovir: The first 7 digits of the drug code are 6250002.
  - ST combination drug: the first 7 digits of the drug code are 6290100
  - Other: Drugs not applicable to the above

- Priority investigation items (important identified risks and important potential risks)

  - Thrombocytopenia: Thrombocytopenia is defined as an adverse event that:.
    - ✧ PT code 10043554 [Thrombocytopenia]
    - ✧ PT code 10035528 [Platelet count decreased]
  - Severe gastrointestinal disorder: Any Grade 3 or higher adverse event meeting any of the following criteria is considered as severe gastrointestinal disorder.
    - ✧ MedDRA SOC code 10017947 (gastrointestinal disorders)
  - Skin disorder: Adverse events that meet any of the following criteria are defined as skin disorder.
    - ✧ MedDRA SOC code 10040785 (skin and subcutaneous tissue disorders)
  - Peripheral neuropathy: Any adverse event that meets any of the following criteria is defined as peripheral neuropathy.
    - ✧ PTs included in the HLT code 10034607 Peripheral neuropathies NEC, excluding neuritis (PT code 10029240)
  - Infections: The following adverse events are defined as infections.
    - ✧ MedDRA SOC code 10021881 (Infections and infestations)
  - Posterior Reversible Encephalopathy Syndrome: Adverse events that meet the following criteria are referred to as posterior reversible encephalopathy syndrome.
    - ✧ MedDRA PT code 10071066 (posterior reversible encephalopathy syndrome)

- Diarrhoea: Adverse events corresponding to MedDRA PT code 10012735 are diarrhoea.
- Vomiting: Adverse events corresponding to MedDRA PT code 10047700 are vomiting.
- Nausea: Adverse events corresponding to MedDRA PT code 10028813 are nausea.

- Timing of onset: Calculated as the date of onset of adverse event (or adverse drug reaction, etc.) − the start date of NINLARO capsules treatment + 1.
- Use in patients with renal impairment: For cases with severe renal impairment and end-stage renal failure.
- Use in patients with liver disfunction: For cases with moderate and severe liver disfunction.
- CTCAE Grade unknown: When the CTCAE Grade is reported as unknown or missing

Analysis Sets

The safety evaluation set will be used as the analysis set for the all case surveillance. The safety population is defined as follows:.

Safety population

In this statistical analysis plan, the "Patients with locked CRFs who received NINLARO capsules and are evaluable for safety" is defined as the safety evaluation set. Of the patients with locked CRFs, those who meet the following conditions will be excluded from the safety evaluation set.

- NINLARO capsules naïve
- Unknown adverse event
- Duplicate case (transferred to another hospital)

1 Number of study sites and number of enrolled patients

1.1 Breakdown of cases

Analysis targets:	All patients enrolled (patients enrolled)	
Analysis item:	Enrolled patients	
	Number of study sites	
	CRF not collected	
	Reason Not Collected	[During the observation period, changes in investigators, health reasons of investigators, etc.]
	Patients with case report forms	
	Patients excluded from safety evaluation *	
	Reason for exclusion (duplicate counting)	[NINLARO capsules was not administered, presence or absence of adverse events was unknown, cases of duplication (cases transferred to other hospital)]
	Patients analyzed for safety *	
	End Status	[Completed, discontinued]
Method of analysis:	For the above analytical variables, the following analyses will be performed to prepare a case composition diagram.	
	For patients registered, the number of medical institutions surveyed will also be calculated. In each survey, medical institutions with different departments were counted as 1 medical institution.	
	*Patients analyzed for safety refer to the "safety evaluation set." Patients excluded from the safety evaluation "refer to patients excluded from the (In this section, patients excluded from the safety evaluation set among the fixed patients).	
	(1) Frequency tabulation	

2 Patient's backgrounds

2.1 Patient's backgrounds

Analysis targets:	Safety population	
Analysis item:	Sex	[Male, female]
	Age (years) *	[< 65 years, 65 ≦ to < 75 years, ≧75 years]
	Duration of disease	[< 1 year, ≥ 1 year to < 3 years, ≥ 3 years to < 5 years, ≥ 5 years, unknown]
	Condition	[Relapsed or refractory, initial onset]
	Types of Multiple Myeloma	[IgG, IgA, IgD, IgE, IgM, Bence Jones type, Kappa, Lambda, non-secretory type, other, unknown]
	Clinical Stage (ISS)	[Stage I, II, III, unknown]
	IMWG diagnostic category	[Symptomatic myeloma, non-secretory myeloma, multiple plasmacytomas, other, unknown]
	ECOG Performance Status※	[0, 1, 2, 3, 4]
	Category of medical care	[Outpatient/inpatient]
	HCV antibody	[Negative, positive, unknown]
	HBs antigen	[Negative, positive, unknown]
	HBs antibody and HBc antibody	[Negative for all, positive for any, unknown]
	HBV DNA	[Negative, positive, unknown]
	Presence or absence of liver dysfunction *	[Absent/Present]
	Grade of liver dysfunction *	[Normal, mild, moderate, severe]
	Presence or absence of renal impairment *	[Absent/Present]
	Grade of renal impairment *	[Normal, mild, moderate, severe, end-stage renal failure]
	Complications	[Absent, present]
	Breakdown of complications (overlapping tabulation)	[Rash, peripheral neuropathy *, gastrointestinal disease, infection *, others]
	Grade of Rash	[Grade 1, Grade 2, Grade 3, Grade 4, Grade unknown]
	Grade of peripheral neuropathy	[Grade 1, Grade 2, Grade 3, Grade 4, Grade unknown]
	Medical history	[Absent, present, unknown]
	Height (cm)	
	Body weight (kg) *	
	BSA※	[< 1.4, ≥ 1.4 to < 1.6, ≥ 1.6]

	Presence or absence of drug therapy before the start of administration of NINLARO capsules	[Absent, present, unknown]
	Breakdown of drug therapy before the start of administration of NINLARO capsules (duplicate counting)	[Other proteasome inhibitors, therapies including portezomib, carfilzomib, IMiDs, lenalidomide, pomalidomide, thalidomide]
	Refractory status of drug therapy before the start of treatment with NINLARO capsules	[Refractory to any prior therapy and not refractory to any prior therapy]
	Breakdown of refractoriness to drug therapy before the start of administration of NINLARO capsules (overlapping tabulation)	[refractory to proteasome inhibitors and IMiDs; refractory to bortezomib; refractory to carfilzomib; refractory to IMiDs; refractory to lenalidomide; refractory to pomalidomide; refractory to thalidomide]
	Number of drug therapy regimens before the start of NINLARO capsules *	[1, 2, 3, 4 or more]
	Number of months from the last month of administration of the last drug therapy before the start of administration of NINLARO capsules to the month of administration of one cycle of NINLARO capsules	
	Presence or absence of radiotherapy before the start of treatment with NINLARO capsules	[Absent/Present]
	Hematopoietic stem cell transplant prior to starting NINLARO capsules	[Absent, present: autologous, present: allogeneic, present: autologous and allogeneic]
	Presence or absence of pregnancy during the observation period (women only)	[Absent/Present]
Stratification items:	Initial dose of NINLARO capsules	[2.3 mg, 3 mg, 4 mg, others]
Method of analysis:	For the above analytical variables, frequency of categorical data will be tabulated for the entire population, for completers, and fordiscontinued patients, and summary statistics will be calculated for continuous data. For items marked with *, the similar analysis will be performed by initial dose of NINLARO capsules.	

3 Conditions of treatment

3.1 Administration status of NINLARO capsules/lenalidomide and dexamethasone

Analysis targets:	Safety population	
Analysis item:	Initial dose of NINLARO capsules	[2.3 mg, 3 mg, 4 mg, others]
	Average dose of NINLARO capsules	
	Average dose of NINLARO capsules per administration (Cycle 1)	
	Average dose of NINLARO capsules per administration (Cycle 2)	
	Average dose of NINLARO capsules per administration (Cycle 3)	
	Average dose of NINLARO capsules per administration (Cycle 4)	
	Average dose of NINLARO capsules per administration (Cycle 5)	
	Average dose of NINLARO capsules per administration (Cycle 6)	
	NINLARO capsules RDI (%)	
	Lenalidomide Initial Dose	[0 mg, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, others]
	Lenalidomide mean dose	
	Lenalidomide Average dose per administration (Cycle 1)	
	Lenalidomide Average dose per administration (Cycle 2)	
	Lenalidomide Average dose per administration (Cycle 3)	
	Lenalidomide Average dose per administration (Cycle 4)	
	Lenalidomide Average dose per administration (Cycle 5)	
	Lenalidomide Average dose per administration (Cycle 6)	
	Lenalidomide RDI (%)	
	Dexamethasone loading dose	[0 mg, 20 mg, 40 mg, others]
	Mean dose of dexamethasone	
	Duration of treatment of NINLARO capsules (Cycle)	[1 cycle, 2 cycles, 3 cycles, 4 cycles, 5 cycles, and 6 cycles]

	Reasons for Discontinuation of NINLARO capsules	[Because the treatment goal was achieved, because the patient stopped visiting the hospital due to the onset of adverse events, because the patient became pregnant, because of insufficient effect, etc.] [Only due to occurrence of adverse event, only due to lack of efficacy, only for other reasons, only due to occurrence of adverse event and lack of efficacy, occurrence of adverse event and other reasons, lack of efficacy and other reasons, 3 or more reasons]
	Presence/absence of Drugs used to prevent recurrence of infection or herpes zoster	[Absent, present]
	Breakdown of Drugs used to prevent recurrence of infection or herpes zoster (multiple counting)	[Famciclovir, valaciclovir, aciclovir, ST combination drug, others]

Method of analysis: For the above analytical variables, frequency of categorical data will be tabulated for the entire population, for completers, and for discontinued patients, and summary statistics will be calculated for continuous data.

The tabulation in the category of When multiple reasons for discontinuation of NINLARO capsules are reported in the same patient [Because the treatment goal was achieved, because the patient stopped visiting the hospital due to the onset of adverse events, because the patient became pregnant, because of insufficient effect, etc.] will be handled as duplicate tabulation. "Other reason" means a reason for discontinuation other than "occurrence of an adverse event" or "lack of efficacy."

3.2 Administration status of NINLARO capsules and concomitant drugs when adverse events occurred

Analysis targets:	Patients in the safety analysis set who experienced adverse events	
Analysis item:	NINLARO capsules dose reduction	[Yes, No]
	NINLARO capsules dose interruption	[Yes, No]
	Discontinuation of NINLARO capsules	[Yes, No]
Stratification items:	Dosage adjustment of Lenalidomide	[Yes, No]

Method of analysis: For the above analytical variables, incidences will be tabulated.

Regarding the administration status of NINLARO capsules at the onset of adverse events, the applicable number of casesevents will be tabulated for each analysis item. In this summary, data by the presence or absence of changes in the dosage and administration of lenalidomide and overall summary results will be presented. In addition, bar charts will be prepared for the above analysis results.

3.3 Tabulation of treatment discontinuation

Analysis targets:	Discontinued patients in the safety evaluation set	
Analysis item:	Reason for Discontin.	[Only due to occurrence of adverse event, only due to lack of efficacy, only for other reasons, only due to occurrence of adverse event and lack of efficacy, occurrence of adverse event and other reasons, lack of efficacy and other reasons, 3 or more reasons]
Stratification items:	Number of cycles at discontinuation	[1, 2, 3, 4, 5, 6]
	Sex	[Male, female]
	Age	[< 65 years, 65 ≦ to < 75 years, ≧75 years]
	Presence or absence of liver dysfunction	[Absent/Present]
	Presence or absence of renal impairment	[Absent/Present]
	Grade of peripheral neuropathy	[Grade 1 to Grade 2, Grade 3 to Grade 4]
	Number of drug therapy regimens before the start of NINLARO capsules	[1, 2, 3, 4 or more]
	Weight	[< 40 kg, ≥ 40 kg to < 50 kg, ≥ 50 kg to < 60 kg, ≥ 60 kg to < 70 kg, ≥ 70 kg]
	BSA	[< 1.4, ≥ 1.4 to < 1.6, ≥ 1.6]
	refractory	[Refractory to any prior therapy and not refractory to any prior therapy] [Refractory to proteasome inhibitors only, refractory to IMiDs only, refractory to proteasome inhibitors and IMiDs, and not refractory to any prior therapy] [Refractory to bortezomib alone, refractory to lenalidomide alone, and others]
	Initial dose of NINLARO capsules	[2.3 mg, 3 mg, 4 mg]
	Average dose of NINLARO capsules	[< 2.3 mg, ≥ 2.3 to < 3 mg, ≥ 3 to < 4 mg, ≥ 4 mg]
	Lenalidomide Initial Dose	[0 mg, > 0 mg to < 10 mg, ≥ 10 mg to < 20 mg, ≥ 20 mg]
	Mean dose of lenalidomide	[0 mg, > 0 mg to < 10 mg, ≥ 10 mg to < 20 mg, ≥ 20 mg]
	Mean dose of dexamethasone	[0 mg, > 0 mg to ≤ 8 mg, > 8 mg to ≤ 20 mg, > 20 mg]

Method of analysis: For the above analytical variable, the following analyses should be performed.

- Frequencies will be tabulated for each cycle at discontinuation and for the pooled data.
- For stratification items other than the number of cycles at discontinuation, frequencies will be tabulated for each number of cycles at discontinuation and for the pooled data.
- At discontinuation The reasons for discontinuation by number of cycles will be output in bar charts.

Other reasons in the category of reasons for discontinuation refer to reasons for discontinuation other than occurrence of adverse events or "lack of efficacy."

4 Matters related to safety

4.1 Occurrence Status of Adverse Events, Adverse Drug Reactions, and Infections

4.1.1 Status of occurrence of adverse events

Analysis targets: Safety population

Analysis item: Adverse events

Method of analysis: For the above analytical variables, the following analyses should be performed for all subjects, completed subjects, and discontinued patients.

（1） Number of patients with adverse events

（2） Number of adverse events

（3） Incidence of adverse events

（4） Type of adverse event

The method of accounting for each analysis is as follows.

[Number of patients with adverse event]

- Number of patients with adverse events.

[Number of adverse events]

- Number of adverse events experienced. If the same adverse event occurs more than once in the same patient, the total number of events will be tabulated.

[Incidence of adverse events]

- Number of patients with adverse events/number of patients analyzed for safety × 100.

[Type of adverse event]

- AEs will be coded using MedDRA/J. The data will be broadly classified by SOC and tabulated by PT. Note that cases in the SOC of “Investigations” will be summarized by HLGT (HLGT codes are sorted in ascending order, but not output) and by PT.
- In the SOC, the number of patients with adverse events and the incidence are presented in internationally agreed order of SOC. If the same SOC occurs more than once in the same subject, the subject will be counted as 1 subject in the SOC.
- For PTs, adverse events should be described in ascending order of PT codes. If the same PT occurs more than once in the same patient, the patient will be counted as 1 patient for the PT.

4.1.2 Occurrence Status of Adverse Drug Reactions/Infections

Analysis targets: Safety population

Analysis item: Adverse drug reactions, etc.

Method of analysis: For the above analytical variables, the following analyses should be performed for all subjects, completed subjects, and discontinued patients .

（1） Number of patients with adverse drug reactions

（2） Number of adverse drug reactions

（3） Incidence of adverse drug reactions

（4） Types of adverse drug reactions, etc.

The method of accounting for each analysis is as follows.

[Number of patients with adverse drug reactions, etc.]

- Number of patients with adverse drug reactions, etc.

[Number of adverse drug reactions]

- Number of adverse drug reactions, etc. that occurred. If the same adverse drug reaction, etc. occurs multiple times in the same patient, the total number of events will be tabulated.

[Incidence of adverse drug reactions, etc.]

- Calculate as the number of patients with adverse drug reactions/the number of patients analyzed for safety × 100.

[Types of adverse drug reactions, etc.]

- Adverse drug reactions, etc. will be coded using MedDRA/J. The data will be broadly classified by SOC and tabulated by PT. Note that cases in the SOC of "Investigations" will be summarized by HLGT (HLGT codes are sorted in ascending order, but not output) and by PT.
- In SOC, the number of patients with adverse drug reactions/infections and the incidence of them are described in the internationally agreed order of SOC. If the same SOC occurs more than once in the same subject, the subject will be counted as 1 subject in the SOC.
- For PTs, the number of patients with adverse drug reactions/infections and the incidence of adverse drug reactions/infections are presented in ascending order of PT codes. If the same PT occurs more than once in the same patient, the patient will be counted as 1 patient for the PT.

4.1.3 Occurrence Status of Adverse Drug Reactions/Infections Leading to Discontinuation of NINLARO capsules

Analysis targets: Safety population

Analysis item: Adverse drug reactions leading to treatment discontinuation

Method of analysis: For the above analytical variable, the following analyses will be performed.

（1） Number of patients with adverse drug reactions leading to treatment discontinuation

（2） Number of adverse drug reactions leading to treatment discontinuation

（3） Types of adverse drug reactions leading to treatment discontinuation

The method of accounting for each analysis is as follows.

[Number of patients with adverse drug reactions, etc. leading to treatment discontinuation]

- Number of patients with adverse drug reactions, etc. leading to treatment discontinuation.

[Number of ADRs leading to treatment discontinuation]

- Number of adverse drug reactions, etc. leading to treatment discontinuation. If the same adverse drug reactions, etc. leading to treatment discontinuation occurred more than once in the same patient, the total number of events will be tabulated.

[Types of adverse drug reactions, etc. leading to treatment discontinuation]

- Adverse drug reactions leading to treatment discontinuation will be coded using MedDRA/J. Summarize by PT. The data will be broadly classified by SOC and tabulated by PT. Note that cases in the SOC of "Investigations " will be summarized by HLGT (HLGT codes are sorted in ascending order, but not output) and by PT.
- In SOC, the number of patients with adverse drug reactions leading to treatment discontinuation and the incidence are shown in the internationally agreed order of SOC. If the same SOC occurs more than once in the same subject, the subject will be counted as 1 subject in the SOC.
- For PTs, the number of patients with adverse drug reactions leading to treatment discontinuation should be presented in ascending order of PT codes. If the same PT occurs more than once in the same patient, the patient will be counted as 1 patient for the PT.

4.1.4 Incidence of adverse events leading to NINLARO capsules discontinuation

Analysis targets: Safety population

Analysis item: Adverse events leading to treatment discontinuation

Method of analysis: For the above analytical variable, the following analyses will be performed.

（1） Number of patients with adverse events leading to treatment discontinuation

（2） Number of adverse events leading to treatment discontinuation

（3） Type of adverse event leading to discontinuation

The method of accounting for each analysis is as follows.

[Number of patients with adverse events of leading to treatment discontinuation]

- Number of patients with adverse events leading to treatment discontinuation.

[Number of adverse events leading to treatment discontinuation]

- Number of adverse events leading to treatment discontinuation. If the same adverse event leading to treatment discontinuation occurred more than once in the same patient, the total number of events will be tabulated.

[Adverse events leading to treatment discontinuation type]

- AEs leading to discontinuation will be coded using MedDRA/J. Summarize by PT. The data will be broadly classified by SOC and tabulated by PT. Note that cases in the SOC of "Investigations " will be summarized by HLGT (HLGT codes are sorted in ascending order, but not output) and by PT.
- In the SOC, the number and percentage of patients with adverse events leading to treatment discontinuation are presented in internationally agreed order of SOC. If the same SOC occurs more than once in the same subject, the subject will be counted as 1 subject in the SOC.

- For PTs, the numbers of patients with adverse events leading to treatment discontinuation are presented in ascending order of PT codes. If the same PT occurs more than once in the same patient, the patient will be counted as 1 patient for the PT.

4.2 Occurrence Status of Adverse Drug Reactions/Infections by Seriousness, CTCAE Grade (Worst Value), Timing of Initial Onset, and Outcome

4.2.1 Seriousness, CTCAE Grade (worst value), time to initial onset, occurrence status of adverse drug reactions/infections by outcome (tabulation of number of subjects)

Analysis targets:	Safety population	
Analysis item:	Adverse drug reactions, etc.	
Stratification items:	Seriousness	[Serious, nonserious]
	CTCAE Grade (worst value)	[Grade 1, Grade 2, Grade 3, Grade 4, Grade 5, Grade unknown]
	Initial onset time	[1 – 7 days, 8 – 14 days, 15 – 21 days, 22 – 28 days or longer] [1 to 28 days, 29 to 56 days, 57 to 84 days, 85 to 112 days, 113 to 168 days, and ≥ 169 days]
	Outcome	[Recovered/resolved, recovering/resolving, not recovered/not resolved, recovered/resolved with sequelae, death, unknown]

Method of analysis: For the above analytical variable, the following analyses should be performed stratified by the stratification factor for the overall population, completed subjects, and discontinued patients.

(1) Number of patients with adverse drug reactions
(2) Number of adverse drug reactions
(3) Incidence of adverse drug reactions
(4) Types of adverse drug reactions, etc.

The method of accounting for each analysis is as follows.

[Number of patients with adverse drug reactions, etc.]

- Number of patients with adverse drug reactions, etc.

[Number of adverse drug reactions]

- Number of adverse drug reactions, etc. that occurred. If the same adverse drug reaction, etc. occurs multiple times in the same patient, the total number of events will be tabulated.

[Incidence of adverse drug reactions, etc.]

- Calculate as the number of patients with adverse drug reactions, etc./the number of patients analyzed for safety × 100.

[Types of adverse drug reactions, etc.]

- Adverse drug reactions, etc. will be coded using MedDRA/J. The data will be broadly classified by SOC and tabulated by PT. Note that cases in the SOC of "Investigations" will be summarized by HLGT (HLGT codes are sorted in ascending order, but not output) and by PT.
- In SOC, the number of patients with adverse drug reactions/infections is shown in internationally agreed order of SOC. If the same SOC occurs more than once in the same subject, the subject will be counted as 1 subject in the SOC. However, one SOC is adopted according to the order of priority at the end.
- For PTs, the number of patients with adverse drug reactions/infections is presented in ascending order of PT codes. If the same PT occurs more than once in the same patient, the patient will be counted as 1 patient for the PT. However, if the same PT occurs in different categories of seriousness, the event will be counted as 1 subject in each category. If the same PT occurs in different categories for reasons other than seriousness, the subject will be counted as 1 subject in the following order of priority.

  CTCAE Grade (worst value): Grade 5 → Grade 4 → Grade 3 → Grade 2 → Grade 1 → Grade unknown

  Timing of initial onset 1: 1-7 days → 8-14 days → 15 to 21 days → 22 to 28 days → ≥ 29 days

  Timing of initial onset 2: 1 to 28 days → 29 to 56 days → 57 to 84 days → 85 to 112 days → 113 to 168 days → ≥169 days

  Outcome: Death → recovered with sequelae → not recovered → recovering → recovered → unknown

4.2.2 Occurrence Status of Adverse Drug Reactions/Infections by Seriousness and Onset Timing (Number of Cases)

Analysis targets:	Safety population	
Analysis item:	Adverse drug reactions, etc.	
Stratification items:	Seriousness	[Serious, nonserious]
	Time of onset	[1 – 7 days, 8 – 14 days, 15 – 21 days, 22 – 28 days or longer] [1 to 28 days, 29 to 56 days, 57 to 84 days, 85 to 112 days, 113 to 168 days, and ≥ 169 days]

Method of analysis: For the above analytical variable, the following analyses should be performed stratified by the stratification factor for the overall population, completed subjects, and discontinued patients.

[Types of adverse drug reactions, etc.]

- Adverse drug reactions, etc. will be coded using MedDRA/J. The data will be broadly classified by SOC. SOC will be described in the internationally agreed order. PT will be described in the ascending order of HLGT codes and the ascending order of PT codes if the SOC is "laboratory " and in the ascending order of PT codes if the SOC is other.
- For PTs, the number of patients with adverse drug reactions/infections is presented in ascending order of PT codes. If the same PT occurs multiple times in the same patient, the total number of events will be tabulated for each category (For example, if a patient had 1 serious and 1 nonserious event of diarrhea, the patient would be counted only once in each category.). Also, when the breakdown of each category is the same in the same patient with the same adverse drug reaction, etc., each shall be counted as 1 case (duplication shall not be deleted).

4.3 Occurrence Status of Adverse Drug Reactions/Infections by Patient's backgrounds and Conditions of Treatment Factor

4.3.1 Occurrence Status of Adverse Drug Reactions/Infections by Patient's backgrounds and Conditions of Treatment Factor

Analysis targets:	Safety population	
Analysis item:	Adverse drug reactions, etc.	
Stratification items:	Age (years)	[< 65 years, 65 ≦ to < 75 years, ≧75 years]
	Duration of disease	[< 1 year, ≥ 1 year to < 3 years, ≥ 3 years to < 5 years, ≥ 5 years]
	Clinical Stage (ISS)	[Stage I, II, III]
	ECOG Performance Status	[0, 1, 2, 3, 4]
	Presence or absence of liver dysfunction	[Absent, present]
	Grade of liver disfunction	[Normal, mild, moderate, severe]
	Presence or absence of renal impairment	[Absent/Present]
	Grade of renal impairment	[Normal, mild, moderate, severe, end-stage renal failure]
	Weight (kg)	[< 40 kg, ≥ 40 kg to < 50 kg, ≥ 50 kg to < 60 kg, ≥ 60 kg to < 70 kg, ≥ 70 kg]
	BSA	[< 1.4, ≥ 1.4 to < 1.6, ≥ 1.6]
	Number of drug therapy regimens before the start of NINLARO capsules	[1, 2, 3, 4 or more]
	Initial dose of NINLARO capsules	[2.3 mg, 3 mg, 4 mg]
	Average dose of NINLARO capsules	[< 2.3 mg, ≥ 2.3 mg to < 3 mg, ≥ 3 mg to < 4 mg, ≥ 4 mg]

Method of analysis: For the above analytical variable, the following analyses should be performed for overall subjects, completed subjects, and discontinued patients by stratification. However and (2) will be tabulated only for the stratification items of age, liver disfunction grade, and renal impairment grade.

(1) Number of patients with adverse drug reactions/infections and the incidence of them

(2) Number of patients with adverse drug reactions by type and incidence proportion

Analyses should be carried out in the following manner.

[Number of patients with adverse drug reactions, etc.]

- Number of patients with adverse drug reactions, etc.

[Incidence of adverse drug reactions, etc.]

- Calculate as the number of patients with adverse drug reactions, etc./the number of patients analyzed for safety × 100.

[Number of patients with adverse drug reactions by type and incidence]

- When "frequency tabulation" is performed

  If an event in the SOC or PT occurs more than once in the same patient, the patient will be counted as 1 patient in the event. The denominator for the calculation of the incidence is the safety analysis population.

4.4 Tabulation and analysis of important survey items

4.4.1 Status of onset of adverse drug reactions/infections corresponding to important survey items

Analysis targets: Safety population

Analysis item: Adverse drug reactions, etc. corresponding to priority investigation items

Method of analysis: For the above analytical variables, the following will be output for each priority investigation item. In addition, the similar tabulation will be performed. The output will be focused on CTCAE Grade ≥ 3.

（1） Number of patients with adverse drug reactions/infections falling under priority investigation items

（2） Number of adverse drug reactions/infections falling under priority investigation items

（3） Incidence of adverse drug reactions, etc. falling under the priority investigation items

（4） Types of adverse drug reactions, etc. corresponding to priority survey items

The method of accounting for each analysis is as follows.

[Number of patients with adverse drug reactions corresponding to key survey items]

- Number of patients who developed adverse drug reactions, etc. corresponding to key survey items.

[Number of events of adverse drug reactions, etc. falling under the priority investigation items]

- Number of adverse drug reactions, etc. corresponding to priority investigation items that occurred. If the same adverse drug reactions, etc. applicable to the priority investigation items occurs multiple times in the same patient, the total number of events will be tabulated.

[Incidence rate of ADRs corresponding to key survey items]

- Calculate as the number of patients with adverse drug reactions, etc. corresponding to priority survey items/the number of patients analyzed for safety × 100.

[Types of adverse drug reactions, etc. falling under the priority investigation items]

- Adverse drug reactions, etc. falling under the priority investigation items will be coded using MedDRA/J. The data will be broadly classified by SOC and tabulated by PT.
- In SOC, the number of patients with adverse drug reactions, etc. that correspond to key survey items and the incidence should be described in the internationally agreed order of SOC. If the same SOC occurs more than once in the same subject, the subject will be counted as 1 subject in the SOC.
- For PTs, the number of patients with adverse drug reactions, etc. falling under the priority investigation items and the incidence will be described in ascending order of PT codes. If the same PT occurs more than once in the same patient, the patient will be counted as 1 patient for the PT.

4.4.2 Data on adverse drug reactions/infections applicable to important survey items by seriousness, CTCAE Grade (worst value), timing of initial onset, and outcome (tabulation of number of patients)

Analysis targets:	Safety population	
Analysis item:	Adverse drug reactions, etc. corresponding to priority investigation items	
Stratification items:	Seriousness	[Serious, nonserious]
	CTCAE Grade (worst value)	[Grade 1, Grade 2, Grade 3, Grade 4, Grade 5, Grade unknown]
	Initial onset time	[1 to 7 days, 8 to 14 days, 15 to 28 days, 29 to 56 days, 57 to 84 days, 85 to 112 days, 113 to 168 days, and ≥ 169 days] [1 day, 2 days, 3 to 7 days, 8 to 14 days, 15 to 28 days, 29 to 56 days, 57 to 84 days, 85 to 112 days, 113 to 168 days, ≥ 169 days] * Use Severe Gastrointestinal Disorders Only * category
	Outcome	[Recovered/resolved, recovering/resolving, not recovered/not resolved, recovered/resolved with sequelae, death, unknown]

Method of analysis: For the above analytical variables, the following analyses should be performed in each subgroup of the stratification factors for each priority surveillance item.

（1） Number of patients with adverse drug reactions/infections falling under priority investigation items

（2） Number of adverse drug reactions/infections falling under priority investigation items

（3） Incidence of adverse drug reactions, etc. falling under the priority investigation items

（4） Types of adverse drug reactions applicable to key survey items

The method of accounting for each analysis is as follows.

[Number of patients with adverse drug reactions, etc. applicable to key survey items]

- Number of patients who developed adverse drug reactions, etc. corresponding to key survey items.

[Number of adverse drug reactions, etc. falling under the priority survey items]

- Number of adverse drug reactions, etc. corresponding to priority investigation items that occurred. If the same adverse drug reaction, etc. occurs multiple times in the same patient, the total number of events will be tabulated.

[Incidence of adverse drug reactions, etc. falling under the priority investigation items]

- Calculate as the number of patients with adverse drug reactions, etc. that corresponds to the priority survey items/the number of patients analyzed for safety × 100.

[Types of adverse drug reactions, etc. corresponding to priority survey items]

- Adverse drug reactions, etc. falling under the priority investigation items will be coded using MedDRA/J. The data will be broadly classified by SOC and tabulated by PT. Note that cases in the SOC of "Investigations " will be summarized by HLGT (HLGT codes are sorted in ascending order, but not output) and by PT.
- In SOC, the number of patients with adverse drug reactions, etc. that correspond to key survey items and the incidence should be described in the internationally agreed order of SOC. If the same SOC occurs more than once in the same subject, the subject will be counted as 1 subject in the SOC. However, one SOC is adopted according to the order of priority at the end.
- For PTs, the number of patients with adverse drug reactions, etc. falling under the priority investigation items and the incidence will be described in ascending order of PT codes. If the same PT occurs more than once in the same patient, the patient will be counted as 1 patient for the PT. However, if the same PT occurs in different categories of seriousness, the event will be counted as 1 subject in each category. If the same PT occurs in different categories for reasons other than seriousness, the subject will be counted as 1 subject in the following order of priority.

  CTCAE Grade (worst value): Grade 5 → Grade 4 → Grade 3 → Grade 2 → Grade 1 → Grade unknown

  Timing of initial onset: 1 to 7 days → 8 to 14 days → 15 to 28 days → 29 to 56 days → 57 to 84 days → 85 to 112 days → 113 to 168 days → ≥ 169 days

  Timing of initial onset *: 1 day → 2 days → 3 to 7 days → 8 to 14 days → 15 to 28 days → 29 to 56 days → 57 to 84 days → 85 to 112 days → 113 to 168 days → ≥ 169 days

4.4.3 Occurrence status of ADRs/infections specified as priority investigation items by seriousness and onset time (tabulation of number of cases)

Analysis targets:	Safety population	
Analysis item:	Adverse drug reactions, etc. corresponding to priority investigation items	
Stratification items:	Seriousness	[Serious, nonserious]
	Time of onset	[1 to 7 days, 8 to 14 days, 15 to 28 days, 29 to 56 days, 57 to 84 days, 85 to 112 days, 113 to 168 days, and ≥ 169 days]
		[1 day, 2 days, 3 to 7 days, 8 to 14 days, 15 to 28 days, 29 to 56 days, 57 to 84 days, 85 to 112 days, 113 to 168 days, ≥ 169 days] *
		Use Severe Gastrointestinal Disorders Only * category
Method of analysis:	For the above analytical variables, the following analyses should be performed in each subgroup of the stratification factors for each priority surveillance item.	

[Types of adverse drug reactions, etc. corresponding to priority survey items]

- Adverse drug reactions, etc. falling under the priority investigation items will be coded using MedDRA/J. The data will be broadly classified by SOC. SOC will be described in the internationally agreed order. PT will be described in the ascending order of HLGT codes and the ascending order of PT codes if the SOC is “laboratory ” and in the ascending order of PT codes if the SOC is other.
- For PTs, the number of patients with adverse drug reactions corresponding to key survey items should be presented in ascending order of PT codes. If the same PT occurs multiple times in the same patient, the total number of events will be tabulated for each category (For example, if a patient had 1 serious and 1 nonserious event of diarrhea, the patient would be counted only once in each category.). Also, when the breakdown of each category is the same in the same patient with the same adverse drug reaction, etc., each shall be counted as 1 case (duplication shall not be deleted).

4.4.4 Status of administration of NINLARO capsules and concomitant drugs due to adverse drug reactions/infections falling under priority investigation items

Analysis targets:	Patients in the safety evaluation set who developed adverse drug reactions, etc. corresponding to each priority survey item	
Analysis item:	dosage modification of NINLARO capsules	[Yes, No]
	Breakdown of changes in the dosage and administration of NINLARO capsules	[Dose reduction only, dose interruption only, discontinuation only, dose reduction and interruption, {dose reduction or/and interruption, and discontinuation]
	Dose Modifications for Lenalidomide	[Yes, No]
	Breakdown of Dosage and Administration Changes for Lenalidomide	[Dose reduction only, dose interruption only, discontinuation only, dose reduction and interruption, {dose reduction or/and interruption, and discontinuation]
Method of analysis:	For the above analytical variables, the following analyses should be performed for each priority investigation item. For each priority investigation item, data will be classified by CTCAE Grade (worst value) of applicable adverse drug reactions, etc. for each analysis item category, and the incidence will be tabulated. In addition, incidence will be tabulated by the presence or absence of a change in the dosage regimen of NINLARO capsules as well as by the presence or absence of a change in the dosage regimen of lenalidomide. If an adverse drug reaction, etc. corresponding to the same priority survey item occurs more than once in the same patient, the total number of events will be tabulated for each category (For example, if 1 event was reduced and 1 event was discontinued in the same patient, the patient will be counted once in each category.). For incidence rates in each category, the denominator should be the number of events per CTCAE Grade (worst value). If the change in the dosage and administration is “delay of the start of administration in the next cycle, ” it should be included in“ treatment suspension.”	

4.4.5 Timing of initial onset of adverse drug reactions/infections corresponding to key survey items

Analysis targets:	Patients in the safety evaluation set who developed adverse drug reactions, etc. corresponding to each priority survey item
Analysis item:	Timing of initial onset of adverse drug reactions, etc. corresponding to key survey items
Method of analysis:	For the above analytical variables, the following analyses will be performed in total. Summary statistics will be calculated for each priority survey item and each adverse drug reaction, etc.

4.5 Tabulation analysis of diarrhoea/vomiting/nausea adverse drug reactions/infections

4.5.1 Administration status of NINLARO capsules and concomitant drugs due to adverse drug reactions of diarrhoea, vomiting, and nausea/infections

Analysis targets:	Patients in the safety analysis set who experienced each of diarrhoea, vomiting, nausea, and other adverse drug reactions	
Analysis item:	dosage modification of NINLARO capsules	[Yes, No]
	Breakdown of changes in the dosage and administration of NINLARO capsules	[Dose reduction only, dose interruption only, discontinuation only, dose reduction and interruption, {dose reduction or/and interruption, and discontinuation]
	Dose Modifications for Lenalidomide	[Yes, No]
	Breakdown of Dosage and Administration Changes for Lenalidomide	[Dose reduction only, dose interruption only, discontinuation only, dose reduction and interruption, {dose reduction or/and interruption, and discontinuation]
Method of analysis:	For the above analytical variable, the following analyses will be performed. Adverse drug reactions of diarrhoea, vomiting, nausea, etc. will be classified by CTCAE Grade (worst value) and analyzed by category, and the incidence will be tabulated. In addition, incidence will be tabulated by the presence or absence of a change in the dosage regimen of NINLARO capsules as well as by the presence or absence of a change in the dosage regimen of lenalidomide. If the same event occurs multiple times in the same patient, the total number of events will be tabulated by category (For example, if 1 event was reduced and 1 event was discontinued in the same patient, the patient will be counted once in each category.). For incidence rates in each category, the denominator should be the number of events per CTCAE Grade (worst value). If the change in the dosage and administration is “delay of the start of administration in the next cycle,” it should be included in “treatment suspension.”	

4.5.2 Time to initial onset of diarrhoea, vomiting, nausea related adverse drug reactions/infections

Analysis targets:	Patients in the safety analysis set who experienced each of diarrhoea, vomiting, nausea, and other adverse drug reactions
Analysis item:	Time to initial onset of adverse drug reactions of diarrhoea, vomiting, and nausea
Method of analysis:	For the above analytical variable, the following analyses will be performed. Summary statistics will be calculated by adverse drug reaction of diarrhoea, vomiting, nausea, etc.

4.6 Case summary of adverse drug reactions with outcome of death

Analysis targets:	Patients with adverse drug reactions resulting in death
Analysis item:	Case Number
	Sex
	Age
	ECOG Performance Status
	Number of prior regimens
	Adverse drug reactions with outcome death
	Number of days from the start of treatment to the onset of adverse drug reactions with outcome death
	Number of days from the start of treatment to death
Method of analysis:	For the above analytical variables, a list will be prepared.

4.7 Incidence of ADRs and infections under the additional pharmacovigilance plan (Attached Form 12)

Analysis targets: Safety population

Analysis item: Important identified risks

Thrombocytopenia

Severe Gastrointestinal Disorders

Skin disorder

Peripheral neuropathy

Important potential risks

Infections

Posterior reversible encephalopathy syndrome

Use in patients with renal impairment

Use in patients with liver disfunction

Stratification items: Seriousness [Serious, nonserious]

Method of analysis: For the above analytical variable, the following analysis should be performed for each stratification factor in accordance with Form 12 (Note) 1 ~ 4 in the Attachment of PSEHB/PED Notification No. 1128 No. 2 dated November 28, 2017.

（1） Number of patients with important identified risks and the incidence of them

（2） Number of patients with important potential risks and the incidence of them

The order of presentation of risk names and risk names shall be in accordance with the List of Terms and Abbreviations.

4.8 Status of onset of adverse events, adverse drug reactions, and infections that correspond to important identified risks and important potential risks

4.8.1.1 Data on adverse events applicable to Safety specifications (tabulation by risk)

Analysis targets: Safety population

Analysis item: Adverse events, etc. falling under the important identified risks (Thrombocytopenia, severe gastrointestinal disorders, skin disorders, peripheral neuropathy) and important potential risks (Infection, posterior reversible encephalopathy syndrome, use in patients with renal impairment, use in patients with liver disfunction)

Stratification items: Seriousness [Serious, nonserious]

Method of analysis: For the above analytical variable, the following analyses should be performed for each risk by stratification factor stratum. Each targeted risk should follow the definition described in Important identified risks and Important potential risks.

[Type of adverse event]

- AEs will be coded using MedDRA/J. The data will be broadly classified by SOC and tabulated by PT. Note that cases in the SOC of "Investigations " will be summarized by HLGT (HLGT codes are sorted in ascending order, but not output) and by PT.
- In the SOC, the number and percentage of patients with adverse events are presented in internationally agreed order of SOC. If the same SOC occurs more than once in the same subject, the subject will be counted as 1 subject in the SOC. However, if the seriousness is different, 1 case shall be counted for each of serious and nonserious cases.
- For PTs, the number of patients with adverse events and the incidence will be presented in ascending order of PT codes. If the same PT occurs more than once in the same patient, the patient will be counted as 1 patient for the PT. However, if the seriousness is different, 1 case shall be counted for each of serious and nonserious cases.

4.8.1.2 Data on adverse drug reactions/infections included in safety specifications (tabulation by risk)

Analysis targets: Safety population

Analysis item: Adverse events, etc. falling under the important identified risks (Thrombocytopenia, severe gastrointestinal disorders, skin disorders, peripheral neuropathy) and important potential risks (Infection, posterior reversible encephalopathy syndrome, use in patients with renal impairment, use in patients with liver disfunction)

Stratification items: Seriousness [Serious, nonserious]

Method of analysis: For the above analytical variable, the following analyses should be performed for each risk stratification group. Each targeted risk should follow the definition described in Important identified risks and Important potential risks.

[Types of adverse drug reactions, etc.]

- Adverse drug reactions, etc. will be coded using MedDRA/J. The data will be broadly classified by SOC and tabulated by PT. Note that cases in the SOC of “Investigations ” will be summarized by HLGT (HLGT codes are sorted in ascending order, but not output) and by PT.
- In the SOC, the number of patients with adverse drug reactions/infections and the incidence of them are described in internationally agreed order of SOC. If the same SOC occurs more than once in the same subject, the subject will be counted as 1 subject in the SOC. However, if the seriousness is different, 1 case shall be counted for each of serious and nonserious cases.
- For PT, the number of patients with adverse drug reactions, etc., and the incidence of them should be described in ascending order of PT codes. If the same PT occurs more than once in the same patient, the patient will be counted as 1 patient for the PT. However, if the seriousness is different, 1 case shall be counted for each of serious and nonserious cases.

4.9 Incidence of adverse drug reactions/infections in post-marketing surveillance (Attached Form 15)

Analysis targets: Patients analyzed for safety

Analysis item: Adverse drug reactions, etc.

Method of analysis: For the above analytical variable, the following analyses should be performed.

（1） Status of post-marketing surveillance, etc.

1） Number of patients included in safety analysis

2） Number of patients with adverse drug reactions

3） Incidence of adverse drug reactions

（2） Types of adverse drug reactions, etc.

1） Number of patients with any adverse drug reactions, etc., and incidence of them (by SOC)

2） Number of patients with any adverse drug reactions, etc., and incidences (by PT)

Adverse drug reactions, etc. will be coded using MedDRA. The SOC will be displayed in internationally agreed order. The PT will be displayed in ascending order of HLGT code and PT code if the SOC is laboratory, and in ascending order of PT code if the SOC is other.

For each analysis, events should be counted in the following manner.

[Number of patients with adverse drug reactions by type and incidence]

- When "frequency tabulation" is performed

  If an event in the SOC or PT occurs more than once in the same patient, the patient will be counted as 1 patient in the event. The denominator for the calculation of the incidence is the safety analysis population.

4.10 Case summary in post-marketing surveillance (Attached form 16)

Analysis targets:	Case report forms collected
Analysis item:	Case Number
	Name of medical institution
	Sex
	Date of birth
	Reason for use (Disease code, disease name)
	Comorbidity (Disease code, disease name)
	Route of administration
	Maximum dose
	Mean dose
	Unit
	Duration of use
	Concomitant drugs (Drug Code, Drug Name)
	Degree of effect
	Reactions (Disease code, disease name, and outcome)
	Survey form number
	Dropout
Method of analysis:	A list of the above analytical variables will be prepared in accordance with Form 16 (Note) 1 ~ 3 in the Attachment of PSEHB/PED Notification No. 1128 No. 2 dated November 28, 2017.

Preparation history (version control)

Version	Date	Author/reviewer	Comments
Original Version	2019.11.25	[redacted]	Preparation of the first version